Study of the Per-Patient Cost and Efficacy of Treatment for Temporomandibular Joint Disorders

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Prepared by:
The Lewin Group

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I. EXECUTIVE SUMMARY

Temporomandibular joint disorder (TMD) encompasses a variety of clinical disorders involving the temporomandibular joint (TMJ), the muscles of mastication, and contiguous tissues. No clear consensus has emerged regarding the definition of TMD, its causes, how to diagnose it, or how best to treat it.

Multiple unrelated, underlying diseases can cause TMD symptoms, although no specific cause can be identified in many patients. Understanding of TMD etiology and pathogenesis is complicated by multiple risk factors, including genetic, environmental, and behavioral ones, that are poorly documented or understood. The natural history of the condition is not well understood. TMD symptoms can increase and abate over time, and can resolve spontaneously without serious long-term effects.

In 1996, the National Institutes of Health (NIH) convened a 15-member, nonfederal, expert panel for a technology assessment conference on management of TMD. After presentation and evaluation of the available evidence, the panel concluded that no treatment for TMD demonstrated effectiveness and that invasive interventions warranted caution, particularly surgery that permanently alters the tooth structure or jaw position. For these reasons, the panel recommended that noninvasive therapies are preferred for the vast majority of patients. The panel further concluded that surgical intervention may be warranted for a small percentage of patients with chronic and substantial dysfunction for whom such noninvasive therapies had failed.

Since 1996, the body of literature on treatments available for TMD has grown. Recently, the Agency for Healthcare Research and Quality (AHRQ) contracted with The Lewin Group to conduct a study of the per-patient cost and efficacy/effectiveness of treatment for TMD. This study is pursuant to a Senate Appropriations Committee request to further clarify this issue, and to follow-up on relevant developments since the 1996 NIH technology assessment conference. To this end, Lewin assembled and reviewed evidence collected from recent (i.e., 1996 to the present) published and gray literature and other pertinent input from stakeholders and other experts. This included a focused literature searching protocol, gathering of other relevant evidence, qualitative grading of the evidence to assess the methodological rigor of the available data, and developing a structured summary of the evidence.

This report confirms certain findings of the 1996 NIH technology assessment conference and of certain other reviews of this subject. Our findings reinforce previous conclusions that few randomized clinical trials (RCTs) or other types of rigorous studies exist for determining the effectiveness of treatments for TMD. Published reports of clinical research on TMD consist primarily of non-randomized uncontrolled trials, case series, case reports, and anecdotal descriptions of treatment techniques. Among the factors affecting the body of evidence on TMD treatments are insufficient understanding or consensus regarding the etiology, course of disease, and diagnosis of TMD. The main findings of this report are as follows.

1. **Etiology unclear.** There is no consensus on the biological cause or etiology of TMD. Clinicians and biomedical scientists believe that multiple unrelated, underlying diseases can cause TMD symptoms, although no specific cause can be identified in many patients. Moreover, a TMD patient may have one or multiple of these conditions concurrently. Understanding of TMD etiology is complicated by identification of risk factors that are poorly documented or understood, including: female sex, age, relationship to pregnancy, use of hormone replacement therapy, injury, surgery, genetic susceptibility, and certain comorbid conditions.

2. **Natural course unclear.** Knowledge regarding the natural course of TMD is limited and controversial. TMD symptoms can increase and abate over time, and can resolve spontaneously without serious long-term effects. There are insufficient longitudinal studies that have followed people with symptoms over the periods of years to provide an accurate understanding of the natural course of TMD. Without this understanding, it is more difficult to demonstrate the net effect of TMD interventions, particularly in the absence of long-term clinical trials (including RCTs) with non-intervention or placebo controls.

3. **Lack of clear diagnostic criteria.** The breadth of signs and symptoms of TMD and inconsistent information about TMD within the clinical communities often confounds diagnosis. The wide range of TMD symptoms may be classified anatomically, by etiology, or by frequency of presentation. While most TMD patients suffer from only mild symptoms, a smaller proportion endure more persistent and severe functional loss and pain. Moreover, there is no widely accepted, standard test currently available to identify TMD. What diagnostic criteria that do exist are not well integrated into standard clinical practice.

4. **Variation in management approaches.** The ambiguity in TMD diagnosis contributes to the use of a variety of diagnostic procedures and their attendant costs. Given its broad clinical manifestations and insufficiently understood etiology, many types of health care providers are involved in management of TMD. As such, the selection of treatment appears to be associated with the type of provider consulted, underlining the lack of consensus regarding appropriate clinical expertise for managing TMD. As a consequence, many patients endure extended searches for a definitive diagnosis and effective treatment, resulting in higher costs and exposing them to potentially adverse treatment effects.

5. **Concerns about adverse effects.** The potential adverse effects of any treatment for TMD must be weighed against any relative benefits that it might confer relative to other TMD treatments, or to no treatment at all. Invasiveness refers to the extent to which an intervention causes permanent changes in the structure or position of the jaw, teeth, or soft tissues. Some treatments, including certain forms of the more invasive treatments, can result in greater pain, disfigurement, and other adverse effects. Given the lack of definitive evidence for the superiority of particular treatments for most TMD patients, more clinicians and researchers argue for employing conservative, reversible approaches to managing most patients with TMD, and progressing to increasingly more invasive ones only upon failure of the more conservative, reversible ones.

6. **Inconsistent outcomes measures.** There is a lack of a well-recognized or uniform set of outcome measures used for evaluating TMD interventions. In general, outcome measures fall into the categories of pain or discomfort; motion or flexibility; clinical visualization; mental health/behavioral; and neurological, neuromuscular, and sleep. Many outcome measures used in TMD studies have not been validated. This confounds attempts to integrate findings across the TMD literature, diminishing the ability to compare results of multiple studies of the same intervention and to generalize findings to clinical practice.

7. **Challenges to determining treatment effectiveness.** Without adequate understanding of TMD, including its varying underlying causes or the ability to use diagnostic criteria for staging TMD in different subgroups of patients, it is more difficult to demonstrate the effect of TMD interventions. To the extent that a treatment is truly effective for a particular subgroup, any attempt to assess its treatment effect in a clinical trial, particularly one with a small sample size, may be masked by its ineffectiveness in other subgroups of TMD patients who are enrolled in the trial. Further, the lack of clear diagnostic criteria and, in some instances, well-defined interventions compromises efforts to integrate results from multiple studies or otherwise draw inferences about the effectiveness or costs of TMD treatments.

8. **Body of evidence limited.** The body of evidence on the effectiveness of TMD treatment generated since 1996 is generally limited and lacking in rigor. This reinforces previous reviews that have concluded that there have been insufficient RCTs and other types of rigorous studies for determining the effectiveness of TMD treatments. Particularly lacking are studies with sufficient power and patient follow-up to detect any true differences in effectiveness among alternative treatments. The 45 studies that met our selection criteria exhibited a largely bimodal distribution, including 15 RCTs and 20 single case studies/anecdotes. As a group, these covered a diverse group of interventions. As a result, the literature on any one type or even group of interventions is limited, and it is difficult to draw well-founded conclusions about how well interventions for TMD work. Many of the existing clinical studies indicate that patients improve following treatment. However, few studies include non-intervention or placebo groups designed to control for such confounding phenomena as placebo effects, regression to the mean, and the spontaneous abatement or cyclical expression of symptoms known to occur in many TMD patients. Very few studies demonstrate sustained superiority of one TMD intervention over another.

9. **Behavior modification and physical therapy.** Available research on behavior modification and physical therapy suggests that some types of interventions can be helpful in reducing pain and increasing function. However, interventions studied range from physical self-regulation to posture correction to an ambiguously described "cognitive therapy." This area of the literature has few studies involving non-treatment control groups, long-term follow-up data, or direct comparisons of alternative methods of behavioral modification and physical therapy.

10. **Pharmaceutical management.** None of the published studies of pharmaceutical management for TMD identified since 1996 indicated significant, positive results. Among

the RCTs conducted since 1996, none demonstrated that pharmaceutical management of TMD symptoms was more effective than placebo for the majority of outcomes considered.

11. **Occlusal therapy.** RCTs examining the benefits of occlusal therapy found mixed results in improving TMD pain and functioning in study participants. In general, these studies found significant improvements relative to baseline in groups wearing various splints or related appliances. There was mixed evidence, including evidence from under-powered studies, that a particular appliance or pattern of wearing an appliance (e.g., day only, night only, or 24 hours) was superior to another. These studies did not have untreated control groups, although one used a control splint.

12. **Surgery.** The three RCTs reported since 1996 focused on the surgical techniques of arthroscopy and/or arthrocentesis. None of these studies included a non-surgical group or a non-treatment group. In all studies, patients were reported to show a statistically significant improvement relative to baseline. For most of the endpoints in each of the studies, the investigators failed to detect a statistically significant difference between the two treatment groups. (One study found arthroscopy to be significantly better than arthrocentesis in improving function, though not pain relief, after one year. Another study comparing alternative arthroscopy techniques found a difference after one month, but no difference at subsequent follow-ups through one year.) That is, while these RCTs showed significant within-group differences from baseline to follow-up, they nearly always failed to demonstrate significant differences among treatment groups. The non-RCT literature on surgery suggests that this option should be considered after other treatment methods have been attempted; in four of the 10 studies, patients had more pain and worse functioning following surgical intervention.

13. **Patients with history of treatment failure.** In any disease area, a consequence of conducting few rigorous studies among a diverse patient population is the inability to gain information about treatment effectiveness among particular patient subgroups. In the instance of TMD, there is little documented involvement of patients with a history of multiple treatments or treatment failures. Clinical studies in this field tend to enroll patients with new disease or with limited comorbidities, in order to limit the potential for these factors to confound any observed treatment effect. This limits opportunities to determine what types of treatment may be effective in salvaging treatment failures, particularly from invasive treatments, or otherwise improving functional status and pain in this special subgroup of TMD patients.

14. **Cost information limited.** The available recent literature on the per-patient costs of TMD is scarce. It is limited to a handful of retrospective studies, including two large case control studies and one large cohort study with a contemporaneous control group. From these, it is possible to derive a rough approximation of direct costs of services associated with TMD treatment, excluding out-of-pocket costs.

15. **Per-patient direct costs.** Among these studies, costs for TMD patients were from 57% to 100% higher than costs for non-TMD patients. Using the findings of the studies as well as

other determinations based on the results presented in them, a rough approximation for total annual per patient costs for TMD patients is $3,100 - $4,700. A rough approximation for the difference between total annual per patient costs for TMD and non-TMD patients is $1,100 - $2,300.

16. **Out-of-pocket costs.** Given that much of the care for TMD is not captured by health plan data sets, per patient out-of-pocket costs are poorly documented. To the extent that various TMD interventions are not covered by insurance, out-of-pocket costs would be expected to comprise a significant proportion of total per-patient costs. The available information concerning out-of-pocket costs for TMD patients is very limited and subject to methodological weaknesses. Nevertheless, it indicates that there is a subgroup of TMD patients experiencing very sizable out-of-pocket costs while pursuing treatment for health conditions that can be painful, debilitating, and intractable.

17. **TMD patient costs higher, but most not TMD-specific.** The limited literature on cost is consistent in two main ways. First, TMD patients use significantly more health care services and generate more costs than non-TMD patients. Second, perhaps contrary to expectation, most of the care used by TMD patients is not directly related to conditions generally recognized to be associated with TMD itself. Together, these findings are consistent with other observations that a significant portion of patients with TMD have other health problems, and that in many patients, TMD itself may be a symptom or other manifestation of one or more other health problems associated with, e.g., the musculoskeletal system, digestive system, mental health, or nervous system.

In the current era of evidence-based health care, the body of evidence on TMD treatment remains largely weak and unfocused. This contributes to ambiguity and variation in patient care for TMD. The limited data on per-patient costs of TMD make it difficult to assess the cost of managing the disorder and its broader economic impact. It is apparent that the additional health care costs generated by patients with TMD are for procedures and services that are not generally recognized to be associated with TMD. The limited evidence on the efficacy/effectiveness of TMD treatment and per-patient costs likely contributes to reluctance of third-party payers to cover TMD treatment and variation in payment patterns among those that do provide coverage. There is growing recognition in the dental profession of the importance of evidence in guiding clinical and payment decisions; however, this remains to be reflected sufficiently in the body of evidence pertaining to management of TMD.

II. INTRODUCTION

As requested by the Agency for Healthcare Research and Quality (AHRQ), The Lewin Group conducted a study of the per-patient cost and efficacy/effectiveness of treatment for temporomandibular joint (TMJ) disorders (TMD). This study is pursuant to a Senate Appropriations Committee request to further clarify these issues, following on the National Institutes of Health (NIH) technology assessment conference on the management of temporomandibular disorders, held in 1996. The conference panel concluded that no treatment demonstrated effectiveness, and that invasive interventions warranted caution, particularly surgery that permanently alters the tooth structure or jaw position (NIH 1996).

For this study, Lewin assembled and reviewed evidence from recent (i.e., since 1996) published and gray literature and other pertinent input from stakeholders and other experts. This included a focused literature searching protocol, gathering of other relevant evidence, interpretation of the evidence to assess the methodological rigor of the available studies, and developing a structured summary of the evidence.

III. WHAT IS TMD?

The TMJs are the sites on either side of the face, just in front of the ears, where the temporal bone of the skull connects to the mandible (lower jaw). The TMJs are supported by ligaments, tendons, and muscles that control jaw movement. The TMJ contains a slick piece of cartilage, known as a disc, and thin film of joint fluid, that allows smooth, low-friction operation of the juncture of the temporal bone of the skull and the rounded hingeball at the end of the mandible known as a condyle. This construction allows the TMJ not only to operate like a hinge, but also to slide forward and backward, and from side to side.

TMD refers to a cluster of medical and dental disorders in the masticatory system, including the TMJ and surrounding tissues, that share many common symptoms. TMD presents with a wide range of symptoms or conditions, including jaw-joint pain, facial pain, headaches, limited mouth opening, closed or open lock of the TMJ, clicking or popping sounds in the jaw joint, and others. TMD is often characterized as chronic, recurrent, nonprogressive pain conditions (Von Korff et al. 1992). Patients with TMD may suffer from a variety of conditions, including systemic-related problems and articular, neuromuscular, neurologic, neurovascular, and behavioral disorders (McNeill et al. 1990; NIH 1996; Shimshak and DeFuria 1998).

IV. ETIOLOGY

There is no consensus on the biological cause or etiology of TMD (Dworkin 1994). Clinicians and biomedical scientists believe that multiple unrelated, underlying diseases can cause TMD symptoms, although no specific cause can be identified in many patients (McNeill 1993; Davies and Gray 1997b; Stohler and Zarb 1999; TMJ Association 2000a). Ekberg (1998) groups the

etiologies of TMD into three categories: anatomical, including occlusion and the TMJ; neuromuscular; and psychogenic. The NIDCR (National Institute of Dental and Craniofacial Research) classifies TMD into:

- myofascial pain (discomfort or pain in the muscles that control jaw function and the neck and shoulder muscles)
- internal derangement of the joint, including dislocated jaw or displaced disc, or physical injury to the condyle (e.g., from blunt trauma)
- degenerative joint disease, such as osteoarthritis or rheumatoid arthritis in the jaw joint (NIDCR 2000)

In internal derangement, the disc inside the TMJ typically lies in front of (anterior to) its normal position. In internal derangement without reduction, the disc does not slip back into its normal position, limiting jaw movement. In the more common internal derangement with reduction, the disc lies in front of its normal position only when the mouth is closed; this movement of the disc often makes a clicking or popping sound.

A TMD patient may have one or multiple of these conditions concurrently. Understanding of TMD etiology is complicated by identification of its risk factors, which are poorly documented or understood. Among the ones that have been suggested for TMD are: female sex, age, relationship to pregnancy, use of hormone replacement therapy, injury, surgery, genetic susceptibility, and certain comorbid conditions (TMJ Association 2000a). However, these are not well documented.

V. COURSE OF DISEASE

Knowledge regarding the natural course of TMD is limited and controversial. TMD symptoms can increase and abate over time, and there are insufficient longitudinal studies that have followed people with symptoms over the course of years to provide an accurate understanding of the natural course of TMD. Without this understanding, it is more difficult to demonstrate the net effect of TMD interventions, particularly in the absence of long-term clinical trials (including RCTs) with non-intervention or placebo controls.

TMD signs and symptoms are often transient, fluctuate, and are self-limiting over time. They may resolve without serious long-term effects, often decreasing among older adults (Ekberg 1998; Greene and Laskin 1983; Mejersjo and Carlsson 1983; Sato et al. 1998; Stohler and Zarb 1999). Little is known about which TMD signs and symptoms will progress to more serious and sometimes intractable conditions (Okeson and Hayes 1986).

A prospective cohort study showed that approximately 76% of patients with disc displacement without reduction became either asymptomatic or improved within 2.5 years, with the balance of patients continuing to be symptomatic (Kurita et al. 1998). Similarly, a 30-year follow-up of a

group of 99 patients who initially had nonsurgical treatment determined that, in the first few years after treatment, the main signs of TMJ osteoarthritis and internal derangement decreased significantly, but that few changes occurred thereafter. The authors concluded that these disorders eventually reach a state of quiescence (de Leeuw et al. 1994).

In a recent review, Barkin and Weinberg (2000) conclude that the signs and symptoms of anterior disc displacement without reduction tend to be alleviated during the natural course of the condition. Further, they indicate that the progression rate of TMD symptoms is not clearly established, and that it is not apparent which patients have the greatest risk of progressing to the more advanced stages. Therefore, consistent with certain other clinicians and researchers, they encourage clinicians to take a patient and clinically vigilant (i.e., conservative and reversible) approach in treating these conditions (Skinner and Neff 1994).

Epidemiological studies indicate that TMD patients have a wide range and varying frequency of signs and symptoms, and only a small percentage of populations with TMD signs and symptoms seek care for these conditions (Dworkin et al. 1990). Significant variability among cases makes diagnosis of TMD complex. Surveys of clinical activity generally indicate that females, primarily those in the 25-44 year age group, are about three times as likely as males to seek care for TMD (McNeill 1993; Rugh JD et al. 1985; Shimshak and DeFuria, 1998).

VI. DIAGNOSIS

The broad collection of signs and symptoms of TMD and inconsistent information about TMD within the clinical communities often confounds diagnosis. TMD symptoms vary widely, and can include the following:

- facial pain; jaw joint pain; often in combination with neck, shoulder, back pain, and/or headaches
- popping, clicking, grating/crackling (crepitus) sounds with movement of the jaw joint
- pain in the joints of the face when opening or closing the mouth, yawning, or chewing
- swelling on the side of the face and/or mouth

  a bite that feels uncomfortable, "off," or as if it is continually changing

  limited opening or inability to open the mouth comfortably
- deviation of the jaw to one side
- the jaw locking open or closed.

TMD may be classified anatomically, by etiology, or by frequency of presentation (Davies and Gray 1997a). The severity of TMD symptoms may also vary a great deal. While most TMD patients suffer from only mild symptoms, a smaller proportion endure more persistent and even debilitating pain (Stohler and Zarb 1999). The most frequently reported reason for seeking treatment for TMD is pain (Agerberg and Helkimo 1987; Dworkin et al. 1990; Ekberg 1998; Magnusson 1984; Wedel 1988). Many of these patients with facial pain have long histories of seeking treatment for their TMD (Turp et al 1988). As is often cited in the literature, symptoms in individual patients can intensify and abate over time in a cyclical fashion, and spontaneously diminish with or without treatment (Barkin and Weinberg 2000; Ekberg 1998; de Leeuw et al. 1994; Kurita et al. 1998; Stohler and Zarb 1999), further complicating characterization of the population of TMD suffers.

Patients may also present with pain dysfunction syndrome, including facial arthromyalgia, TMJ dysfunction syndrome, myofascial pain dysfunction syndrome, craniomandibular dysfunction, or myofascial pain and dysfunction (Davies and Gray 1997b). As noted above, TMD patients usually present with multiple of these symptoms.

Among the more commonly used diagnostic approaches are:

- medical and dental history to assess overall health, family history, and related problems regarding, e.g., stress, bruxism, bite problems

  physical exam involving, e.g., palpation of myofascial muscles and jaw joint, measurement to assess any limitation of mouth opening, use of a stethoscope to hear any clicking sounds in the jaw joint

- imaging tests, e.g., transcranial x-rays, computed tomography (CT), or magnetic resonance imaging (MRI) for bone structure, fractures, joint damage, or tumors; and magnetic resonance imaging for detailed views of soft tissue damage in discs and ligaments

  dental casts to determine how muscle or jaw problems such as bruxism might have affected jaw alignment and bite

There is no widely accepted, standard test currently available to identify TMD. In cooperation with the University of Washington, the NIDCR developed a set of research diagnostic criteria (RDC) in 1992. However, these criteria have not been verified by the NIDCR (Dworkin and LeResche 1992; NIDCR representative, November 11, 2000). The RDC were developed given the realization that practitioners and researchers need to recognize and include both the physiological and psychosocial aspects of TMJ pain and dysfunction in a diagnostic system. The RDC placed diagnostic factors into two categories: physical factors and psychosocial factors. In this system, physical factors are based on clinical signs, such as muscle and/or joint tenderness, limited movement, and joint sounds. Psychosocial factors are based on symptoms, such as pain and disability, depression, and other nonspecific complaints. Physical factors are further divided into muscle disorders (tenderness with and without limited opening), disc displacements (anterior displacement with reduction and anterior displacement without reduction with and without

limited opening) and other joint disorders (e.g., arthralgia and osteoarthritis). Psychosocial factors include pain intensity and disability graded on a visual analog scale (VAS; typically a standardized scale numbered 1 to 10 that allows patients to describe their pain and assess changes in it), psychological status as revealed by a depression score, and the presence and prevalence of physical symptoms considered unrelated to the TMD (e.g., gastric acidity).

In general, these and other sets of diagnostic criteria are not well integrated into standard clinical practice and are not accepted by many in the dental profession. This is due, in part, to the discordance between the wide scope of the diagnostic criteria and the specialization among individual clinicians seeing patients presenting with TMD symptoms. In particular, some in the profession, who consider themselves more clinically than academically based, regard the RDC as being too oriented toward a psychosocial perspective rather than a pathophysiological one (Keropian 2001). This contingent considers that psychological factors are present as a secondary element only in a small percentage of TMD patients. Similarly, there is broad disagreement on the relative importance of jaw posture in diagnosis and treatment.

According to the NIDCR (2000), in most cases, the patient's description of symptoms, combined with a simple physical examination of the face and jaw, provides information useful for diagnosing these disorders in about 90% of cases. However, definitive diagnoses that point to established, effective treatments are relatively uncommon. Based on the literature and our expert interviews, only one etiology – blunt trauma to the TMJ or surrounding area – was cited as having a clear and established treatment approach. However, only a handful of articles in the recent literature involve patients with trauma-induced TMD (e.g., TMJ disc derangement following a motor vehicle accident; McNamara et al. 1996; TMD following a gunshot wound to the face; Horrell et al. 1997).

Organized efforts also have been undertaken to develop criteria for evaluating impairment and disability associated with the TMJ and functions involving the teeth, mouth, jaws, and related structures more broadly. These have been done with the intention of influencing or being incorporated into authoritative documents of the American Medical Association (AMA) and the World Health Organization, used in professional decisions about injury, illness, disease or disorder related impairment, disability, and handicap status. In 1993, the *AMA Guides to the Evaluation of Permanent Impairment* incorporated the TMJ and the masticatory musculature; however, professional groups whose members treat TMD regard this as vague about evaluation methods and without objective criteria. In 1997, with a focus on a future revision of the *AMA Guides*, representatives of these groups developed a *Guide to Evaluation of Permanent Impairment of the Temporomandibular Joint* (Phillips et al. 1997; Chase and Rosenoer 1999). Development and acceptance of such criteria are strongly influenced by professional issues, including relationships among different dental specialties as well as perceived clinical domains of physicians and dentists, and implications of these for patient care and payment.

As indicated in multiple studies of TMD patients, the ambiguity in TMD diagnosis contributes to the use of a variety of diagnostic processes and their attendant costs (Glaros et al. 1995; Shimshak and DeFuria 1998). Patients often get involved in extended, costly searches for

definitive diagnoses and effective treatment (Garro et al. 1994). This is exacerbated by overlap between the fields of medicine and dentistry, and lack of clinician awareness about the condition.

Insufficient understanding of the etiology and course of TMD, along with insufficient diagnostic criteria, confound patient identification and determination of effective treatments. The variety of symptoms that may qualify patients as having TMD, or that the course of the disease may be transient or self-limiting, may fluctuate, or may progress to being increasingly serious and intractable, suggest that there are subgroups of TMD patients who may respond differently, including not at all, to a given treatment.

VII. TREATMENTS FOR TMD

For the purpose of this report, The Lewin Group used a taxonomy of existing treatments identified in the literature. As shown in Table 1, four broad categories of treatment include: behavior modification and physical therapy, pharmaceutical management, occlusal (mouth closure/bite) adjustment (non-surgical), and surgery.

Table 1: Therapeutic Taxonomy

Therapeutic Category	Treatment Examples	
Behavior modification and physical therapy	• resting jaw • applying ice and heat • exercising jaw • biofeedback • relaxation techniques • counseling, support groups	• jaw exercises • postural training • mobilization • electrical stimulation • ultrasound
Pharmaceutical management	• aspirin • nonsteroidal anti-inflammatory drugs • muscle relaxants	• psychotropics • narcotics
Occlusal adjustment (non-surgical)	• splint • stabilization appliance	• orthodontics • restorative work
Surgery	• arthroscopy • arthrocentesis	• soft tissue repair • joint restructuring

Adapted from The Staywell Company (2000). TM disorders: a guide to managing your temporomandibular joint problem [Brochure]. San Bruno, CA: McNeill C and Rudd P.

Surgery usually entails surgical repair of the disc, e.g., reshaping and sewing it back into place, repair of connective tissue, or restructuring or replacing part or all of the disc or condyle. Arthroscopy involves the insertion of specially designed instruments through small incisions to visualize and operate on the joint in a minimally-invasive manner, as opposed to open-joint

surgery. Arthocentesis involves the use of small needles to flush the joint and inject an anti-inflammatory agent.

A. Different Clinicians and Variation in Treatment

Given its broad clinical manifestations and insufficiently understood etiology, many types of health care providers are involved in management of TMD. In seeking effective treatment, individual patients may see several types of providers, ranging from dentists to maxillofacial surgeons to biofeedback therapists. As such, the selection of treatment appears to be associated with the type of provider consulted. This underlines the lack of consensus regarding appropriate clinical expertise for managing TMD. A survey conducted by The TMJ Association (2000c) asked respondents to note from which among a list of 29 types of professionals they had sought care for TMD. In the large case control study of enrollees in a large northeastern insurance plan (Shimshak et al. 1997), patients with at least one of four ICD-9 codes associated with TMD were seen by a variety of types of clinicians far more often than their matched controls. The clinicians included chiropractors, physical therapists, dentists, otolaryngologists, general and family practitioners, psychiatrists, and others. In a study on the treatment-seeking patterns of patients with facial pain, Turp et al. (1998) found that each patient sought treatment for the condition from an average of about five clinicians. As a group, these represented more than 40 categories, including family physicians, neurologists, ear-nose-throat specialists, chiropractors, osteopaths, rheumatologists, physical therapists, psychologists, acupuncturists, and psychiatrists.

B. Progressing from Least to Most Invasive Treatment

The treatments in Table 1 are shown in approximate order from least invasive to most invasive of the face, jaw, or joint. Invasiveness refers to the extent to which an intervention causes permanent changes in the structure or position of the jaw, teeth, or soft tissues. Some treatments, including certain forms of the more invasive treatments, are associated with greater pain, disfigurement, and other adverse effects (Stohler and Zarb 1999; American Pain Society Meeting 2000). Treatment invasiveness is generally inversely related to reversibility. The potential adverse effects of any treatment must be weighed against any relative benefits that it might confer relative to other TMD treatments, or to no treatment at all.

As documented in this report, the body of evidence on the effectiveness of TMD treatment is generally limited and lacking in rigor. Particularly lacking is evidence demonstrating relative differences in effectiveness among these treatments. As such, an increasing number of clinicians and researchers argue for employing conservative, reversible approaches to managing most patients with TMD, and progressing to increasingly more invasive ones only upon failure of the more conservative, reversible ones (Neff 1995; Skinner and Neff 1994). As stated by Stohler and Zarb (1999), "The rationale to escalate care from simple to complex treatments in patients with unmet treatment expectations is questionable, because the superiority of invasive procedures over conservative therapies has not been demonstrated by any kind of systematic

research." They conclude that a low-tech and conservative approach is warranted in most patients. The NIDCR (2000) states that surgical treatments should be avoided where possible.

VIII.OUTCOME MEASURES

There is a lack of a well-recognized or uniform set of outcome measures used for evaluating TMD interventions. Also, many outcome measures used in TMD studies have not been validated, i.e., shown to detect changes in TMD status in an accurate and reliable manner. This confounds attempts to integrate findings across the TMD literature, diminishing the ability to compare results of multiple studies of the same intervention and to generalize findings to clinical practice (LeResche et al. 1997; Stohler and Zarb 1999). In general, outcome measures fall into the categories of: pain or discomfort; motion and flexibility; clinical visualization; mental health/behavioral; and neurological, neuromuscular, and sleep. Outcome measures used in the TMD literature are shown in Table 2. The majority of studies identified in this review used measures of pain and jaw motion and flexibility to assess patient outcomes.

Table 2: Outcome Measurement Tools Used in TMD Studies

Outcome Measure	Method or Example
Pain and discomfort	Visual analog scales of pain (various); Subjective pain diary Relative verbal pain descriptions; Pain Questionnaire; McGill Pain Questionnaire (MPQ) (Melzak 1987); West Haven-Yale Multidimensional Pain Inventory (MPI) (Kerns et al. 1985)
Motion and flexibility	Jaw opening, pain on palpation, joint noises, etc.
Clinical visualization	Radiographic imaging (e.g., CT, MRI)
Mental health and behavioral	SCL-90R measurement of psychological status (Derogatis 1992); Pittsburgh Sleep Quality Index (Buysse et al. 1989); Helkimo's Anamnestic Dysfunction Index (Helkimo 1974); Helkimo's Clinical Dysfunction Index (Helkimo 1974); Symptom Severity Index (SSI); Craniomandibular Index (including Dysfunction Index and the Muscle Index) (Fricton and Schiffman 1986); Beck Depression Inventory(BDI) (Beck et al. 1961); Oral-Parafunctional Habits Scale (Turk et al. 1996); Modified Symptom Severity Index
Neurological, neuromuscular, and sleep	Pressure algometer (to measure pressure pain thresholds); polysomnographic recording (of sleep patterns); electroencephalographic (EEG) and electromyographic (EMG) recorder; measurement of electrical activity (electrodes/monitor)

Aside from the lack of standardized and validated outcome measures is the question of whether or not these measures capture the impact of TMD on the lives of patients. LeResche et al. (1997) have suggested use of more specific outcomes related to pain and its consequences, such as pain intensity, affective aspects of pain, pain-related coping, pain behaviors (i.e., expressive behaviors, activity limitation, and use of health services), and pain-related disability and life interference.

IX. SELECTED IMPLICATIONS FOR STUDY DESIGN AND INTERPRETATION

One of the challenges posed by a vaguely defined and diverse patient population is the difficulty of establishing a uniform patient sample when drawing patients for a clinical trial from larger populations with apparent signs or symptoms for TMD. One implication of this is that investigators use very broad patient inclusion criteria, in which it is likely that patients with a wide variety of signs and symptoms, and perhaps an equally wide variety of underlying diseases or conditions, are included in a study of a treatment for TMD. If the particular treatment is truly beneficial for a particular subgroup of this broadly constituted patient sample, but is not beneficial for other subgroups, then the treatment effect is more likely to be diluted or masked by the larger non-responding patient population. Clinical trials with small sample sizes are particularly subject to this weakness. This decreases the internal validity of the study findings, which in this instance are more likely to be negative. The design, implementation, and

interpretation of clinical trials of TMD treatments is compromised by the absence of sufficient understanding of the etiology and course of TMD and diagnostic criteria that could be used for staging or other clinically meaningful distinctions among subgroups of TMD patients.

Conversely, the breadth of TMD symptoms and diagnostic ambiguity have implications for very restrictive inclusion criteria. Unless a study is drawing from a very large population, such as a managed care organization with hundreds of thousands of enrollees, it may be difficult to identify a treatment group of sufficient size to provide the statistical power to detect any true treatment effect. The findings of studies with such small groups are also more vulnerable to patient noncompliance and dropouts. To the extent that the treatment used in the study is found to be effective in the selected treatment group, these findings will have limited external validity to the broader TMD population. The management and interpretation of patient noncompliance and dropouts, regardless of the size of the trial, can compromise its rigor and the validity of its findings (Whitney and Dworkin 1997).

The latter implication of selection criteria is exemplified in a study by Ekberg et al. (1996) in which only 39 patients satisfied the selection criteria from an initial population of 2,012 TMD patients. Similarly large exclusions were noted in Ekberg et al. (1998b) with 60 subjects from 1,904 TMD patients, Goudot et al. (2000) with 62 subjects from 720 TMD patients, and Magnusson and Syren (1999) with 26 subjects from 1,344 TMD patients. In an RCT reported by Magnusson and Syren (1999), the investigators chose to forgo carrying out a statistical analysis due to patient dropouts and noncompliance with the established treatment regimen.

There are many instances where a body of evidence on the effects of a health care intervention on certain diseases or conditions comprises conflicting findings or inconclusive findings due to studies having sample sizes that are too small for detecting any true treatment effects. In such instances, it may be possible to pool study results or patient-level data using meta-analysis or other integration approaches. However, these usually require having a group of studies involving a particular intervention used in populations with the same or similar indications. The lack of clearly defined diagnostic criteria and interventions compromises efforts to integrate results from multiple studies or otherwise draw inferences about the effectiveness or cost of TMD treatments.

The potential discrepancy between the more "ideal" conditions in some RCTs and other investigations of TMD treatments conducted in research settings and the conditions of routine clinical settings in which TMD is managed may diminish the validity of some of the available literature. This is recognized by researchers and was emphasized by certain of the clinicians and researchers interviewed for this report. RCTs conducted under conditions and lacking sufficient duration may not add greatly to understanding "real-world" care, which often involve long-term treatment utilizing combinations of therapies and flexible pharmaceutical dosages (Stohler and Zarb 1999; Schiffman et al. 1996). While this is a common debate in clinical research, it is particularly relevant in this case due to the heterogeneous nature of TMD cases and treatments.

X. STUDY METHODOLOGY

Two main tools were used to gather information for this report: stakeholder input and an extensive review of the literature. An initial review of the literature was used to help us identify relevant issues in the treatment of TMD and to inform the questions we developed for interviews of stakeholders and other experts. These discussions helped to guide the search strategy for the focused literature review.

A. Stakeholder Input

Lewin solicited expert opinion from NIDCR staff, representative payers, provider associations, and patient advocacy groups. The purpose of this task was to gain input from stakeholders regarding available treatments, pertinent outcome measures (for safety/risk, morbidity, quality of life, etc.), economic measures (for costs, productivity, etc.), and relevant sources of evidence. The interviews served also to more clearly define the scope of this effort. An expert from the field of dentistry with peer-reviewed published research reports on TMD helped to guide our stakeholder outreach and review of the literature.

Stakeholders contacted included NIDCR staff, the medical directors of four major payers (Kaiser Permanente, NW Region; Arkansas Blue Cross and Blue Shield; Blue Cross and Blue Shield of Kansas; and United Healthcare), four provider associations (American Dental Association; American Academy of Head, Neck, and Facial Pain; American Chiropractic Association; and the Foundation for Chiropractic Education and Research), and patients (i.e., The TMJ Association). Lewin solicited the views of these stakeholders with regard to available treatments, the costs and effectiveness of these treatments, and relevant supporting evidence. Not all stakeholders who were contacted were interviewed. In some cases, stakeholders declined, some indicating that it was inappropriate for them to be interviewed on this subject (Table 3).

Table 3: Stakeholders and Other Experts

Stakeholder	Contact and Title	Interviewed
Center for Health Research, Kaiser Permanente, NW Region	Alex White, D.D.S., Oral Health Services Researcher	Yes
Blue Cross and Blue Shield of Kansas	S. Satya-Murti, M.D., Medicare Medical Director	Yes
United Healthcare	Dick Justman, M.D., National Medical Director	Yes
Arkansas Blue Cross and Blue Shield Association	Jim Adamson, M.D., Corporate Medical Director	Yes
The TMJ Association	Terrie Cowley, President	Yes
National Institute of Dental and Craniofacial Research (NIDCR)	Kenneth Gruber, Ph.D., Chief of Chronic Disease Branch	Yes
American Dental Association	No contact	Declined
American Chiropractic Association	No contact	Declined
Foundation for Chiropractic Education and Research	No contact	Declined
American Academy of Craniofacial Pain (formerly American Academy of Head, Neck, and Facial Pain)	Larry Tilley, D.M.D., President Elect	Yes
Private practice (Washington, DC)	Peter Neff, D.D.S., Sc.D.	Yes

B. Focused Literature Review

Articles relevant to the per-patient costs and efficacy of available treatments for TMD were systematically collected and reviewed for the period January 1996 through January 2001. Multiple search strategies in MEDLINE and the Cochrane database were used. We limited our search to articles in English (English abstracts for non-English articles were excluded) and to human trials only. We also limited the focus to articles in which the primary focus was treatment of TMD or costs associated with treatment of TMD. Specifically excluded were articles related only to complications resulting from treatment or the etiology and diagnosis of the TMD. Additional articles suggested during our stakeholder interviews that were not identified in our literature review but that met the inclusion criteria were included (e.g., Carlson et al. in press). Table 4 outlines the search terms used.

Further, we conducted a search of the ClinicalTrials.gov database, maintained by the National Library of Medicine (NLM), using the search term "temporomandibular joint disorders" to identify any studies currently in the planning stages. Three relevant studies were identified, which are noted below.

1. *Inclusion and Exclusion Criteria*

Selection criteria were chosen to limit the literature reviewed to only studies that concern the efficacy and/or the per-patient costs of treatment for TMD. Only studies that met all of the selection criteria were included in our review. We attempted to strike a balance in developing selection criteria that were broad enough to capture the breadth of TMD and its treatments, yet not so broad as to encompass cranio- or maxillofacial disorders and treatments that may be only marginally, or not at all, related to TMD, or that would yield a review containing information that is difficult to compare and synthesize (Khan et al.).

Table 4: Literature Search Methods

Database Type	Database Name	Years	MeSH
National Library of Medicine	MEDLINE	1996-Present	[Temporomandibular joint disorders *or* Temporomandibular joint dysfunction syndrome *or* Craniomandibular disorders *or* Facial neuralgia] AND [Economics (subheading and MeSH) *or* Costs *or* Cost analysis *or* Cost (text word) *or* Cost-benefit analysis *or* Cost effectiveness] AND [Therapeutics *or* Treatment] AND [Randomized controlled trial *or* Editorial *or* Longitudinal study *or* Clinical trial *or* Meta-analysis *or* Control *or* Trial]
The Cochrane Collaboration	The Cochrane Library	1996-present	Temporomandibular joint disorders Randomized controlled trial Clinical trial Treatment

C. Organizing the Literature

During preparation of the literature review, we developed a matrix detailing the types of articles identified (Appendix A: Evidence Table). Articles reporting on treatment efficacy are organized by type of study (e.g., RCTs, nonrandomized trials with concurrent controls, etc.). The small number of articles reporting on cost of TMD precluded organization in this manner (see Overview of Cost Literature). Information collected on each article included the following.

- Title
- Author(s)
- Source
- Modality
- Sample size
- Study duration
- Follow-up
- Blinding
- Multi-site
- Sample characteristics
- Outcome measures
- Benefit of the study
- Cost of treatment (if stated)

After standardizing the information collected from each article, we organized the body of literature by study design. The categories of study type are based on use of an evidence-based approach in which greater study validity is attributed to more rigorous methodology. The classification of therapies was loosely adapted from the literature and from clinical educational documents prepared for patients (e.g., Stohler and Zarb 1999; The Staywell Company 2000).

Investigators use various study designs to determine the effectiveness of specific treatment approaches. While there are many variations of study designs, they can be categorized into several main, well-recognized groups that are distinguished by key methodological attributes such as being prospective vs. retrospective, controlled vs. uncontrolled, and randomized vs. nonrandomized. We categorized the literature into these categories, as follows, listed in general order of most to least rigorous design.

- Randomized controlled trial (RCT)
- Non-randomized trial with concurrent control
- Non-randomized trial with historical control

  Case control or adjusted cohort study
- Case series

  Case study or anecdote
- Expert opinion

In general, double-blinded, multi-site, large sample, randomized controlled trials (RCTs) are considered to be the gold standard of methodological rigor for determining treatment efficacy. These studies should also include sound inclusion and exclusion criteria to achieve uniformity, sufficient power to permit valid generalization, and appropriate handling of missing data and

patient dropouts (i.e., discussion or use of an intention-to-treat analysis). Of course, it is not always possible to conduct studies with all of these attributes; for example, while it is often possible and desirable to conduct single- or double-blinded studies of pharmaceutical therapies, it is usually not possible or acceptable to conduct blinded or placebo-controlled studies of surgical interventions. Furthermore, studies that are well designed are not necessarily well conducted.

Finally, in evaluating the evidence on effectiveness, we further classified articles by treatment methodology as described in section VII above. For example, all RCTs assessing behavioral interventions were evaluated, followed by articles examining behavioral interventions that were not RCTs.

XI. FINDINGS

A. Efficacy and effectiveness literature

1. Overview

Seventy-two studies were identified in our initial literature search. Of these, 27 were subsequently excluded, 10 of which were RCTs, because they did not meet our selection criteria (see below). An additional RCT was included in our review that was identified by one of our stakeholders and is currently in press. Of the non-RCTs excluded from review, 10 studies were outside the scope of our study, i.e., TMD was not the focus of the study. Five non-RCTs were excluded because they did not involve an intervention for TMD. One non-RCT was excluded because it was a pilot study, and one was excluded because it was in Italian.

In total, 15 RCTs, two nonrandomized trials with concurrent controls, one case control, one case series, 20 single case studies, and six expert opinions satisfied our inclusion and exclusion criteria. Table 5 provides the distribution of study type by year.

Table 5: Distribution of study type by year

Study Type	1996	1997	1998	1999	2000	2001	Totals
Randomized clinical Trial	4	3	2	3	2	1*	15
Nonrandomized trial with concurrent control	1	1	0	0	0	0	2
Nonrandomized trial with historical control	0	0	0	0	0	0	0
Case control or adjusted cohort study	1	0	0	0	0	0	1
Case series	0	0	1	0	0	0	1
Single case study or anecdote	2	3	4	10	1	0	20
Expert opinion	1	3	0	1	1	0	6
Total	9	10	7	14	4	1	45

* Carlson et al., in press

2. *Randomized Clinical Trials*

The initial search identified 25 reports of RCTs. Five were excluded because TMD was not the primary focus of the investigation; the subjects had other disorders, e.g., bruxism, headache, or arthritis (Marklund and Franklin 1996; Tegelberg and Kopp 1996; de Andre et al. 1998; Vallon and Nilner 1997; Treacy 1999) or the study was not specifically an investigation of an intervention for TMD (Nemeth et al. 2000; Rodrigues-Garcia et al. 1998; Kirveskari et al. 1998; Ekberg and Nilner 1999). One study was excluded because it was published in German (Umstadt et al. 1998). One study was excluded because it was an analysis of material already included in this review (Ekberg et al. 1998a).

Fifteen reports of RCTs of treatments for TMD were found that met our selection criteria. Of these, four studied the effectiveness of behavior modification techniques and/or physical therapy in treating TMD, four focused on the effectiveness of pharmaceutical management to treat TMD, four investigated the effectiveness of occlusal therapies, and three investigated the effectiveness of surgical techniques on TMD (Appendix A).

All but two of the study populations consisted of patients who had been referred for treatment for TMD symptoms (e.g., orofacial pain, TMJ locking, and/or clicking). In two studies (Denucci et al. 1998; Komiyama et al. 1999), the nature or basis of identifying the study population is not described. Information about previous TMD treatments was provided in the majority of studies. In three cases, explicit mention was made of previous treatment as an exclusionary criterion or that no patient in the study had previously been treated for TMD (Ekberg 1998b; Komiyama et al. 1999; Magnusson and Syren 1999). Three studies on surgical interventions note that non-

invasive measures were attempted before surgery was undertaken (Fridrich et al. 1996; Goudot et al. 2000; Miyamoto et al. 1999). Three studies made no mention of previous treatment history (Davies and Gray 1997a; Davies and Gray 1997b; Shin and Choi 1997).

The number of patients included in the trials varied from 19 to 101, with a mean of 47 patients. The number of patients was 20 or fewer in three studies (Appendix A). In four studies, it was not apparent from the patient selection criteria whether patients received treatment before the trial that would have confounded the results (Davies and Gray 1997a; Davies and Gray 1997b; Miyamoto et al. 1999; Shin and Choi 1997). In one study (Goudot et al. 2000), the selection criteria were vague. The remaining studies included sufficiently described selection criteria.

The average duration of treatment was 13.4 weeks (excludes certain studies because the investigation did not take place over a period of time, i.e., surgery with follow-up and pre- post-treatment studies; Fridrich et al. 1996; Goudot et al. 2000; and Miyamoto et al.; Schiffman et al. 1996; Shin and Choi 1997; Turk et al. 1996). Follow-up occurred in eight of the 15 studies, ranging from six months to four years (Appendix A). The methods used to randomize patients into treatment groups were described vaguely or not at all in all but two studies (Carlson et al. in press; Ekberg et al. 1998b). Six of the studies were double-blinded and two studies were single-blinded (Appendix A). None of the RCTs reviewed was conducted in a multi-site setting.

3. Therapeutic Taxonomy

In the sections that follow, we discuss the literature in terms of the therapeutic taxonomy described above, focusing primarily on RCTs. For each of these therapeutic categories, summaries of individual RCTs are presented along with a collective summary of the non-RCTs at the end of each section. Table 6 provides a summary of the studies by therapeutic modality (Note: Table 6 includes all study types, not just RCTs). Three expert opinions did not fit into any one therapeutic modality and were therefore excluded from Table 6. Wilkinson 1997 provided an overview and commentary of treatments for TMD, Laskin 1997 draws a distinction between disorders of muscular origin and those of joint origin, and how treatment should account for this. Lastly, Greene et al. 1999 argue for treating patients in a biopsychosocial framework, by approaching treatment with conservative and scientifically validated modalities.

Table 6: Distribution of study type by therapeutic modality*

Study Type	Behavior Modification/ Physical Therapy	Pharmaceutical Management	Occlusal Adjustment (non-surgical)	Surgery
Randomized clinical trial	4	4	4	3
Nonrandomized trial with concurrent control	1	0	0	1
Nonrandomized trial with historical control	0	0	0	0
Case control or adjusted cohort study	1	0	0	0
Case series	0	0	0	1
Single case study or anecdote	4	0	8	8
Expert opinion	1	0	1	1
Total	11	4	13	14

*Three studies did not fall into any one of these categories (i.e., there are only 42 studies counted in this table).

a) Behavior modification and physical therapy

Four studies dealt specifically with behavior modification or physical therapy (Carlson et al. in press; Komiyama et al. 1999; Turk et al. 1996; Wright et al. 2000).

Carlson et al. (in press) studied 44 patients randomized into two groups: one received physical self-regulation training and another received standard dental care. A non-intervention control group was not established for this trial. Study duration was three weeks. Subjective patient-reported data on pain and psychological status were collected using validated measurement tools at six and 26 weeks. A statistically significant difference in outcome was found between treatment groups, and both groups improved significantly from baseline. Physical self-regulation was found to be useful in decreasing pain, increasing incisal opening without pain, and decreasing psychological dysfunction in TMD patients. Twelve of the original 56 subjects (21%) dropped out before study completion; follow-up data were not collected from these subjects and an intention-to-treat analysis was not performed. All participants were maintained on any medications they were taking prior to the study.

Komiyama et al. (1999) investigated posture correction in 60 patients randomized into three groups: one received cognitive behavioral treatment methods, one received cognitive behavioral methods with posture correction, and a non-intervention control group. Subjective data of pain intensity, mouth opening, and disturbance in daily life were collected monthly, and patients were followed for 12 months. The posture correction group showed statistically significant initial improvement over the non-intervention group, but this difference diminished over the course of the trial, and at 12 months there were no statistical differences between any of the groups. All groups improved over the course of the study, but a statistical comparison to baseline values was not reported. Nine patients dropped out of the trial before completion, although the published

report did account for them (i.e., analyses were conducted both including and not including study dropouts).

Wright et al. (2000) studied 60 TMD patients randomized into two groups: one group received posture training with TMD self-management instructions and a control group that received TMD self-management instructions only. A non-intervention control group was not established for this study. Objective and subjective data were collected using validated methods, and patients were followed for four weeks. Statistically significant improvement was found for symptom severity, maximum pain-free opening, pain threshold measurements, and patients' perceived TMD and neck symptoms. Therefore, the study indicated that posture training was a useful adjunct to self-management instructions in diminishing symptoms of TMD in patients with a primary muscle disorder.

Turk et al. (1996) evaluated the efficacy of a "tailored treatment protocol," involving the unique combination of cognitive therapy to use of stress management, biofeedback, counseling, and an intraoral appliance. Forty-eight subjects were randomized into two groups: one group received an intraoral appliance, stress management with biofeedback, and counseling ("non-tailored group") and a second group received the same treatment as the first, plus cognitive therapy ("tailored treatment group"). A non-intervention control group was not established for this study. Objective and subjective data were collected, and patients were followed-up at six months. Both groups improved significantly from baseline measurements. Additionally, a statistically significant difference in outcome was found between groups, supporting the efficacy of a tailored treatment protocol in treating TMD. The tailored treatment protocol significantly decreased pain, depression, and medication use relative to the control group. Data was collected using several standardized and validated methods, and a treatment credibility analysis was conducted to determine patient confidence in their treatment.

The studies summarized here suggest that some methods of behavior modification and physical therapy may be useful in treating the symptoms of TMD patients, though the absence of non-intervention control groups obviated the possibility of determining whether these treatments would be any better than no intervention, particularly in the long-term. Only Komiyama et al. included a control group that received no intervention. Both Komiyama et al. and Wright et al. found a significant improvement in patients treated with posture correction compared to controls in short-term measurements, but the 12-month data from Komiyama et al. showed that this difference diminished greatly over time. The Wright et al. study was not conducted over a long enough period to observe this possibility. Carlson et al. found that physical self-regulation was useful in decreasing symptoms of TMD, but this study too was of short duration. Similarly, Turk et al. showed that, for six months, a tailored treatment regimen (i.e., including cognitive therapy) was significantly more useful in treating TMD symptoms than was a non-tailored approach. Long-term studies that include non-intervention control groups are needed to show that behavioral and physical therapy are more useful than non-intervention in treating TMD symptoms, though the therapies outlined here may be useful in alleviating symptoms for short periods of time (i.e., up to six months).

1. Non-RCTs

Five studies were identified that used behavior modification or physical therapy and were not RCTs. One study was a non-randomized trial with concurrent control (Conti, 1997). A second study utilized the case control study design (Gramling et al., 1996). The remaining four studies were case series (see Appendix A). In addition, there was one expert opinion article that focused on behavioral and physical therapy (Dworkin, 1997). Dworkin reviewed the literature related to behavioral interventions and found that such interventions are a component of most chronic pain management programs and that such programs can be effective for TMD patients.

Conti (1997) studied 20 patients receiving either low-level laser therapy (in which a probe emitting a low energy output laser is directed over the TMJ for short durations) or a placebo treatment in which the probe is used but turned off. Though the laser therapy was hypothesized to reduce pain and increase mandibular function by affecting metabolic activation of cells and tissues in the TMJ, the investigators found no differences in pain or functioning. Gramling et al. (1996) studied 16 patients, nine of whom received habit-reversal training consisting of a seven session group training program to teach patients how to detect, interrupt, and reverse maladaptive oral habits. The comparison group constituted the six patients that met the study inclusion criteria but chose not to enroll in the study. Results after six months indicated that the therapy lowered ratings of highest weekly pain at statistically significant levels, and reduced average daily pain and increased the number of pain-free days at levels that approached but did not reach statistical significance. Friedman (1997) published a case study on one patient who was taught TMJ manipulation and exercise for a 6-week period. At the end of the treatment period the patient had reduced pain and increased functioning as indicated by maximum jaw opening. Horrell et al. (1997) studied the use of passive motion therapy in two juvenile patients, one of whom had TMJ consequent to a traumatic facial injury. Over the three-month period, both patients utilized a device to restore joint mobility resulting in increased functioning as measured by maximum jaw opening at the beginning and end of the treatment period. Martini et al. (1996) reported on the successful use of repetitive manipulation technique over a two-week period in three patients with acute and chronic jaw locking. Yokoyama reported on the short-term use of linear polarized near-infrared radiation in four patients with rheumatoid arthritis-affected TMJ pain. Pain was eliminated in each patient, and in three patients, functioning was improved as measured by maximum jaw opening.

The non-RCT literature indicated generally positive results for behavioral therapy, though most studies did not include a nontreatment group, had small samples, and followed patients over very short time periods.

b) Pharmaceutical management

Pharmaceutical management of TMD was investigated in four RCTs (DeNucci et al. 1998; Ekberg et al. 1996; Schiffman et al. 1996; Shin and Choi 1997).

DeNucci et al. (1998) studied 20 patients in a randomized, two-period, within-subject, crossover study to investigate the effect of triazolam, a sedative/hypnotic, on sleep improvement and pain relief in TMD patients. Objective and subjective data were collected using validated methods, and the study was conducted over two weeks. Statistically significant improvement was found with use of triazolam versus placebo for sleep-related endpoints (e.g., sleep quality, restfulness, and time spent in stage-2 sleep), though no improvement was seen in objective or subjective pain measures. The study indicated that improvement in sleep quality does not affect pain report in TMD patients, thereby failing to support a relationship between sleep disturbances and chronic orofacial pain.

Ekberg et al. (1996) studied diclofenac sodium, a nonsteroidal anti-inflammatory drug (NSAID), as an alternative treatment for TMJ pain in 32 subjects randomized into two groups: one receiving diclofenac sodium two or three times a day and another group receiving a placebo. Objective and subjective data were collected, and patients were followed for two weeks. The treatment group showed a statistically significant improvement over the placebo group for tenderness to palpation of the masticatory muscles and frequency of TMJ pain at one of three evaluation visits. This difference diminished by the end of the two weeks, and no significant differences were found between groups for any other endpoints. At the end of the study, 38% of subjects in the treatment group and 25% of subjects in the placebo group reported an improved condition, though this difference was not statistically significant. This trial did not demonstrate that diclofenac sodium should be used as a primary treatment for TMD pain.

Schiffman et al. (1996) studied the effects of iontophoretic delivery (introduction of medication ions through tissue via electrical current) of dexamethasone phosphate, a synthetic adrenocortical steroid, on TMD symptoms in 27 subjects randomized into three groups: a treatment group (dexamethasone phosphate and lidocaine hydrochloride), a control group (lidocaine hydrochloride), and a placebo group (pH-buffered saline). Objective and subjective data were collected immediately preceding treatment and one week after treatment using standardized and validated measures. A long-term follow-up of study subjects was not conducted. The treatment group showed significant post-treatment improvement over the other two groups for only Helkimo's Anamnestic Dysfunction Index scores (a symptom checklist that assesses the subject's symptoms associated with the stomatognathic system). No statistically significant difference was found between groups for any of the other outcomes. These results suggest that dexamethasone phosphate with lidocaine hydrochloride may be effective in improving mandibular function, but not in reducing pain. It is not clear that this effect continues over time.

Shin and Choi (1997) investigated the effects of indomethacin (a nonsteroidal anti-inflammatory indole derivative) phonophoreses (introduction of medication through tissue via ultrasound massage) on pain relief in the TMJ. Twenty subjects were randomized into two groups: one group received ultrasound massage to the TMJ using 1% indomethacin cream as a conducting medium and one group received ultrasound massage using a placebo cream as a medium. Objective and subjective data were collected from subjects pre- and post- treatment, and no follow-up of study subjects was conducted. No statistically significant differences in outcome were found between the two study groups. Ultrasound massage with indomethacin cream was

found to be useful in relieving pain in the TMJ, but not significantly more so than a placebo cream.

None of the four RCTs summarized here showed that pharmaceutical management of TMD symptoms was more effective than a placebo for the majority of outcomes considered. Moreover, none of these studies followed subjects for more than 52 weeks to determine longer-term effects of treatment. DeNucci et al. (1998) found that, while triazolam improved sleep quality, this did not translate into relief of pain symptoms in TMD patients. Ekberg et al. (1996) found that diclofenac sodium does not provide a significant relief of TMD symptoms over placebo. Schiffman et al. (1996) showed that while dexamethasone phosphate and lidocaine hydrochloride provided a significant improvement in Helkimo's Dysfunction Index scores, it did not significantly improve any other outcomes investigated. Lastly, Shin and Choi (1997) found no significant post-treatment improvement using indomethacin cream over use of a placebo cream when conducting ultrasound massage. All four studies had small sample sizes and were of short duration (Appendix A).

c) Occlusal adjustment

Four RCTs specifically investigated the effectiveness of non-surgical occlusal adjustment therapies in treating TMD (Davies and Gray 1997a; Davies and Gray 1997b; Ekberg et al. 1998b; Magnusson and Syren 1999).

Davies and Gray (1997a) studied 70 TMD patients using an anterior repositioning splint to address TMJ disc displacement with reduction. All patients received splints and were randomized to three different treatment groups that wore the splint only during the day, only at night, or for 24 hours a day. Data collected included self-reported subjective assessment of pain, joint sounds, and range of motion over a three-month period. All three treatment groups were reported to have improved relative to baseline in terms of pain, functioning, and the presence of disc sounds. The group wearing the splint for 24 hours a day experienced greater rates of improvement than the other two groups at levels that were statistically significant.

In their second study, Davies and Gray (1997b) studied 70 TMD patients, diagnosed with pain dysfunction syndrome, using a stabilization splint. All patients received splints and were randomized to three treatment groups that wore the splint only during the day, only at night, or for 24 hours a day. Data collected included self-reported subjective assessment of pain, joint sounds, and range of motion over a three-month period. All three treatment groups were reported to have improved relative to baseline in terms of pain, functioning and the presence of disc sounds, though there was no statistically significant difference in outcomes among the three treatment groups.

Ekberg, et al. (1998b) studied 60 treatment-naive patients who were diagnosed with TMD reported to be of arthrogenous origin, and randomized to receive either a stabilization or control appliance used at night. Both patients and the evaluating physician were blinded to the type of appliance being worn by the patients over a 10-week period. Subjective data were collected on

functioning and pain and objective data were collected on presence of TMJ sounds. Both the treatment and control groups experienced statistically significant improvements relative to baseline in all outcome measures, while the treatment group showed improvements in some measures of pain and functioning that were greater than in the control group at statistically significant levels. Almost one-third of the control group and 7% of the treatment group reported exacerbation in pain during the study period.

Magnusson and Syren (1999) studied 26 patients randomized to receive either therapeutic jaw exercises or interocclusal appliance therapy for a 24-week study. At the mid-point of the study a new "combined" treatment group was created with five patients due to persistent symptoms in this subset. Two-thirds of each treatment group and all members of the combined therapy group were also taking analgesics during the study period. Subjective outcome data were collected by mail survey from one to four years later. The authors report improvements in pain and functioning at the end of the initial study period and at follow-up one to four years later for all study groups, though no statistical analyses were presented and the treatment groups had similar outcomes.

RCTs examining the benefits of occlusal therapy found mixed results in improving TMD pain and functioning in study participants. Davies and Gray (1997a,b) conducted two studies with different types of splints, with each study examining the effectiveness of different durations or timing of splint use, with no untreated control group. In both of these short-term studies, patients in all groups improved relative to baseline. In the first study, the patients wearing the splint for 24 hours a day had significantly greater improvement compared to the other groups (Davies and Gray 1997a). Eckberg et al. (1998b) also found patients in both the stabilization appliance group and the control appliance group improved , though the treatment group experienced certain significant reductions in pain and functioning relative to the group with a control appliance. Magnusson and Syren (1999) studied patients using an interocclusal appliance, physical therapy, or combination therapy in a six-month study and found improvements in each therapy group, though statistical differences were not assessed due to small sample sizes. Overall, occlusal therapy appeared to have positive outcomes relative to baseline levels in the short term (e.g., less than six months), though splints did not emerge as being clearly superior to control groups receiving no therapy.

1 Non-RCTs

Nine non-RCTs dealing with non-surgical occlusal therapies for treating TMD met the inclusion criteria for this review. Eight of those studies were case reports and one was an expert opinion (Keller 1996). Keller 1996 presents a discussion of the use of orthodontics in treating TMD, making a plea that professionals involved in this area work together and maintain an atmosphere of open discussion of issues relevant to TMD and the treatment of TMD. Keller further presents a case for the use of orthodontics in treating TMD, providing an account of approximately 400 clinical results in orthodontic treatment for patients who had been diagnosed with TMD.

Of the eight case reports, five demonstrated positive outcomes for the patient or patients. Two studies reported that the treatment failed to correct the TMD, and one study did not report outcomes. Treatment duration ranged widely from 12 weeks to 10 years. The small number of studies and anecdotal nature of the reports did not allow for analysis of trends in the findings. A more detailed summary of the case reports is presented below.

DeGuchi et al. (1998) treated a patient with a chin cup to control mandibular growth and flat plane occlusal splint therapy to relieve pain and relax musculature over a period of approximately 10 years. Therapy in this case relieved the TMJ pain and helped achieve more normal movement in the mandible. Dylina (1999) treated a patient using occlusal appliance therapy for approximately three years to treat facial/joint pain and headaches. At three years, the patient was pain free. Festa et al. (1998) treated two patients with a functional distraction appliance for approximately five months in one case and two weeks in another to treat locking, reduction in mouth opening, pain, and mandibular shift. (This spring-loaded oral appliance had the intended effect of continuously and progressively stretching the muscle fibers adjacent to the TMJ, thereby reducing muscular tension, and ultimately realigning the structures of the TMJ.) No outcomes were reported because this study presented only preliminary findings. Joondeph (1999) reported on a patient treated with a mandibular anterior repositioning appliance for one year and three months to diminish TMJ pain, soft tissue noise, and myofascial discomfort. Follow-up evaluations at three and seven years showed that the patient had completely relapsed to pre-treatment condition. Keng (1996) treated a patient with a provisional occlusal acrylic resin splint for two years to relieve pain, clicking, and an over-closure of the mandible. The patient's condition was stable and asymptomatic at a two-year follow-up examination. Learreta (1999) treated a patient with an occlusal splint for nine months and with a transcutaneous electrical neurostimulator (TENS) unit to treat TMD having arisen from a streptococcus infection. An MRI one year after initial treatment showed clinical improvement in TMJ positioning. Sato et al. (1997) report on the treatment of a patient with anterior mandibular positioning for approximately two years and one month to treat disc displacement. Condylar position was corrected by anterior repositioning, but the treatment failed to correct the disc displacement. Lastly, Zuccolotto et al. (1999) treated a patient with a modified occlusal splint with a "sliding plate design" for approximately 12 weeks. The device was successful in reducing TMD pain.

d) Surgery

Three published RCTs investigated the efficacy of surgical techniques to diminish symptoms resulting from TMD (Fridrich et al. 1996; Goudot et al. 2000; and Miyamoto et al. 1999).

Goudot et al. (2000) studied 62 new patients suffering from "TMJ pain and dysfunction syndrome" who had been unresponsive to noninvasive therapy for six months. The patients were randomized to receive either arthroscopy or arthrocentesis. The study measured self-reported functional status and change in pain as reported on a visual analog scale one year after surgery. Both groups improved significantly from baseline. The groups did not differ significantly from

each other in pain reduction, but arthroscopy was found to be significantly more effective in improving functional outcomes.

Fridrich et al. (1996) compared arthroscopy and arthrocentesis for the treatment of TMD. Nineteen patients were randomized into two groups: one group received arthroscopic lysis and lavage under general anesthesia, and the other group received arthrocentesis, hydraulic distention, and lavage under intravenous sedation. Objective and subjective data were collected, and patients were followed 26 months postoperatively. The overall success rates were 82% for the arthroscopy group and 75% for arthrocentesis group. However, there were no statistically significant differences in outcome between the two groups for any of the parameters evaluated. Therefore, while both modalities were associated with improved TMD symptoms, their therapeutic success rates were not significantly different. The authors did not address the possibility that the small sample size of this trial may not have provided sufficient power to detect any true difference between treatments.

Miyamoto et al. (1999) prospectively compared two techniques of arthroscopic surgery for advanced internal derangement of the TMJ. In this trial, 101 patients were randomized into two groups: one group had arthroscopic lysis and lavage (ALL) and one group received arthroscopic lysis and lavage plus arthroscopic anterolateral capsular release (ALLCR). Objective and subjective data were collected at 1, 3, 6, and 12 months postoperatively. The only statistically significant difference between groups was found at one month, when the ALLCR group had greater mouth opening than did the ALL group. Both groups had significantly less pain in the joint and better jaw opening one year postoperatively, demonstrating that both techniques were useful in the management of advanced internal derangement of the TMJ. Given their similar outcomes, the authors recommended using the less invasive method of lysis and lavage.

All three of these RCTs focused specifically on the surgical techniques of arthroscopy and/or arthrocentesis. None of these studies included a non-surgical group or a non-treatment group. For most of the endpoints in each of the studies, the authors failed to detect a statistically significant difference between the two treatment groups. Goudot et al. (2000) found a statistically significant difference between treatment groups in improving function though not in pain relief. They concluded that arthroscopy provides better results for functional treatment than does arthrocentesis. All three studies reported statistically significant improvements relative to baseline.

1. Non-RCTs

Ten articles reporting on surgical therapy in study designs other than RCTs met the inclusion criteria. One expert opinion report focused on the use of surgery (Barkin and Weinberg, 2000) and the lack of long-term follow-up in most studies of surgery. Only one study was cited as having long-term outcomes reported, though this study was only for arthrocentesis on acute TMJ closed lock (Nitzan 1991). The authors discussed arthroscopic and open surgical techniques as well as injection of fluids.

McNamara et al. (1996) published the only study of patients with TMD as a result of a traumatic injury (motor vehicle accident) that met the inclusion criteria. Twenty patients who received either arthroscopic surgery with midlaser therapy TMJ/occlusal stabilization post-surgery or only midlaser treatment and TMJ/occlusal stabilization were compared. Follow-up data was collected at three years. Though a statistically significant difference was not detected between groups, patients in both treatment categories had reduced pain and disc derangement following therapy. Hirota (1998) reported on 15 patients with internal derangement of the TMJ who were studied for presence of arachidonic acid metabolites or cytokines in the synovial fluid of the joint. The case series explored the impact of injecting hyaluronic acid to reduce inflammation. Pre- and post-treatment data collected over the two-week study period indicated significant reductions in pain, jaw clicking, and improvements in degree of mouth opening. There was no long-term follow-up or nontreatment comparison group included in the study. Grubbs (1999) reported a case study of a patient with a history of TMD, though no current pain, that underwent osteotomy to "align her teeth." Eight months following surgery, the patient had chronic pain and her condition had worsened. Hori et al. (1999) reported on three patients that underwent split osteotomy; all had greater pain and reduced functioning at 3, 6, and 9 months post-treatment. Israel and Scrivani (2000) reported on one patient treated with increasingly invasive therapy (from analgesics to discoplasty with distal repositioning) with poor long-term outcomes at one year following therapy. Itoh et al. (1999) published a case report on a pediatric patient treated over a five year period with increasingly invasive therapy, from occlusal splint therapy to orthodontic surgery. The patient achieved proper occlusion and was free of TMD symptoms at five years. Kondo and Aoba (1999) reported on two pediatric patients who received occlusal splints and orthopedic surgery of the neck muscles; they were followed for eight years and were found to be symptom free. Lida et al. (1998) reported a case study of a patient with partial bone necrosis in the TMJ presumed to be due to repeated injection of sodium hyaluronate. The patient underwent a sequestrectomy and was found to have increased functioning at one month post-operation. Spinazze et al.(1998) report on a patient unsuccessfully treated with increasingly invasive procedures (i.e., analgesic therapy, surgery, and gap arthroscopy). Thomas and Tucker (1999) review evidence for increasingly invasive therapy in some patients and describe the experience of a pediatric patient who ultimately received surgery for TMJ with positive long-term results.

Six of the 10 non-RCT studies of surgical intervention for TMD found that surgery was successful in reducing pain and increasing function. One of these studies (McNamara et al. 1996) was limited to patients with the specific cause of TMJ being traumatic injury to the face. Its positive findings were consistent with the assertion by multiple stakeholder interviewees that surgery can be appropriate for a narrowly defined population, i.e., those with a clear etiology who are deemed appropriate for surgical treatment by their physician). Even so, that single non-randomized study since 1996 of 20 patients constitutes limited evidence. The series of 15 patients with internal derangement of the TMJ who received hyaluronic acid showed positive outcomes, but were followed for only two weeks. Of the remaining eight reports involving surgery for one to three patients each, half showed improvement and half showed no improvement or had worsening outcomes.

Among the small number of clinical studies of treatments for TMD patients, there is little documented involvement of patients with a history of multiple treatments or treatment failures. As is the case for many areas of health care in which new or alternative treatments are being evaluated, clinical studies in this field tend to enroll patients with new disease or with limited comorbidities, in order to limit the potential for these factors to confound any observed treatment effect. This limits opportunities to determine what types of treatment may be effective in salvaging treatment failures, particularly from invasive treatments, or otherwise improving functional status and pain in this special subgroup of TMD patients.

B. Cost literature

1. Overview

Main categories of health care costs include direct health care costs (including medical, dental, and other), direct non-health care costs, indirect costs, and intangible costs. Direct health care costs refer to changes in resource use attributable to health care interventions such as the costs of physician services, hospital services, pharmaceuticals, and associated administrative costs. Direct non-health care costs refer to other costs associated with accessing care, such as for patient transportation and child care. Indirect costs are usually those associated with productivity losses due to illness or death.[1] Intangible costs are those of pain and suffering; although they are rarely quantified in economic terms, pain and suffering can be quantified as part of quality of life and health status measures.

Ideally, measurement of direct health care costs would entail actuarial determinations of the various resource inputs for providing health care. However, making true cost determinations can impractical and expensive. Most studies use more readily available surrogates for true costs, such as health care prices, charges, or payments.

Health care costs are often weighed against health care benefits or outcomes in such analyses as cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis. These typically involve comparisons of marginal changes in health outcomes as a function of marginal changes in health care costs. At a macroeconomic level, cost analyses involve determinations of, e.g., the impact of a disease or of health care interventions for various diseases on national health care expenditures.

The economic focus designated for this study is the per-patient costs of TMD treatment. These are direct health care costs of treatment. Given the content of the earlier literature and the expectations of our stakeholder interviewees, however, we anticipated a limited body of literature on this topic. Therefore, we were prepared to refer to published as well as unpublished

[1] For example, a study conducted in Finland found that patients with TMD had higher rates of self-reported sick leave, in addition to higher health services utilization. The most common reported causes of sick leave were influenza and psychological causes (Kuttila et al. 1997).

literature that was available on other types of costs or other types of cost analyses if it included information that could provide insight regarding per patient costs of TMD treatment.

Consistent with the experience of several of our stakeholder interviewees and earlier literature, we found the available literature on the per-patient costs of TMD to be scarce. A MEDLINE search using such search terms as "costs and cost analysis," "cost," "cost-benefit analysis," and "cost-effectiveness" combined with the search terms related to TMD yielded 94 articles published since 1996 (see Methodology section). Of these 94 articles, five were determined to be relevant to this report (Kuttila et al. 1997; Moenning et al. 1997; Scarfe et al. 1998; Shimshak and DeFuria 1998; Shimshak et al. 1997). Stakeholders interviewed for this report called our attention to two additional relevant reports (The TMJ Association, unpublished; White et al. in press). Appendix B provides a summary of these seven studies.

Though not directly relevant to the purpose of this study, it is worth noting that we found no indication of the magnitude of national spending on TMD, although a 1993 study estimated that total U.S. spending for treatment of orofacial pain was roughly $32 billion per year (Sears 1993).

2. Per-patient Costs

There is no consensus or recognized convergence in the published literature or other sources that we identified regarding the direct health care costs associated with TMD treatment. However, a small set of retrospective studies of TMD patients drawn from large health plans, including two case control studies and one cohort study with a contemporaneous comparison group, provide information than can be used to derive estimates of the per patient costs of TMD treatment. These studies, along with a small number of other studies pertaining to costs, are described below. The ongoing NIDCR-funded RCT of four types of treatment for TMD being conducted by Schiffman et al. (2000, December) is collecting direct-cost data as part of the study.

a) Study of a large insurer, 1989-1990

In a retrospective case control study using the administrative database of a major medical insurer, Shimshak et al. (1997) compared the medical claims profiles and costs of 1,819 matched pairs of patients with and without TMD. The study covered patients who had been enrolled continuously in the Master Health Plus health plan, offered by Blue Cross Blue Shield of Massachusetts, during the two-year period 1989-1990. Members of this plan received first-dollar coverage for physician services, inpatient and outpatient care, and prescription drugs. However, the benefit for TMD disorders was limited to a reimbursement of $750 over a two-year period. Dental claims were not available for analysis, since the insurer did not offer dental insurance. (Some care from dentists that qualified under the medical insurance plan was included.)

The TMD cases (patients with TMD), were selected on the basis of having at least one paid claim (physician or other professional) in the two-year period having a diagnosis of one of the following four ICD-9-CM codes: Temporomandibular joint disorders (524.60), Dislocation of jaw, closed (830.00), Dislocation of jaw, open (830.10), and Sprain of jaw (848.10). Of these

four codes, nearly 95% of the claims for the TMD cases were diagnosed with 524.60. A total of 1,819 TMD patients were identified with these codes. The control patients (non-TMD patients) were matched to the cases based on age, sex, relationship to subscriber, and employer group.

Across the population of 1,819 TMD patients, the total payments for all types of claims combined during the two-year period amounted to $10.8 million, compared to $5.4 million for the matched non-TMD population, i.e., a ratio of 2:1. This amounted to a mean of $5,945 per TMD patient and $2,973 per matched control patient for the two-year period, a statistically significant difference ($p<0.0001$). Of the $10.8 million in total payments for all types of claims among TMD patients, only $483,000, or less than 5%, was attributable to the four ICD-9 codes for TMD. Though not reported by the investigators, this amounts to just $266 per TMD patient for the two-year period. Clearly, most of the care provided for patients with TMD is not associated with the procedure or diagnosis codes used to identify TMD patients. (The cost figures provided in this study appear to be in current dollars, not adjusted for inflation.)

In addition to the four TMD codes that were used to select the 1,819 cases, the investigators examined payments associated with an additional 29 diagnoses that were defined as being related to TMD. (This set of codes was drawn from the set of 29 "TMJ-related" diagnoses identified by Blue Cross Blue Shield of Minnesota and used to define coverage for all health plans in that state.) Among the 29 TMJ-related diagnoses, the codes with the most claims were: Myalgia (729.10), Mixed tension/vascular (346.90), rheumatoid arthritis (714.00), Muscle spasm (728.55), and Muscle tension headache (307.81). Among the TMD cases, 408 claimants for any of these additional codes accounted for payments of $83,519, while among the controls, 123 claimants accounted for payments of $29,829, for a ratio of 2.8 in total payments. Thus, the payments for TMD patients for claims for the four main TMD codes plus the 29 additional TMJ-related diagnoses raises the cost of TMD-related care to about $567,000, or 5.25% of total health care expenditures for TMD patients (Table 7).

Table 7: ICD-9-CM Codes attributed to TMD

	ICD-9 Code	Diagnosis Description
TMJ Diagnostic Codes	524.60	Temporomandibular joint disorders
	830.00	Dislocation of jaw, closed
	830.10	Dislocation of jaw, open
	848.10	Sprain of jaw
"TMJ-Related" Diagnostic Codes*	306.80	Bruxism
	307.81	Muscle tension headache
	316.00	Psychological factors
	346.00	Migraine, classic
	346.10	Migraine, common
	346.20	Cluster headache
	346.80	Migraine, hemiplegic
	346.90	Mixed tension/vascular
	350.10	Trigeminal neuralgia
	352.10	Glossopharyngeal
	352.90	Occipital
	446.50	Temporal arteritis
	524.10	Asymmetry of jaw
	524.20	Dental arch malrelationship
	524.40	Malocclusion, unspecified
	714.00	Rheumatoid arthritis
	715.00	Osteoarthritis, generalized
	716.10	Arthropathy, traumatic
	728.00	Myotis, infective
	728.81	Myotis, interstitial
	728.85	Muscle spasm
	729.10	Myalgia
	733.99	Eagles syndrome

Adapted from Shimshak et al. 1997

* Six TMJ-related diagnostic codes were not utilized in the study and are excluded from the table

The ratio of total payments for cases compared to controls was 2.2 among females and 1.7 among males. During the two-year period, the number of claims for any of the four ICD-9 codes for TMD among the cases was 4.9 for females and 2.9 for males, although the mean amount paid per claim was $57 for females and $76 for males. Just 13% of the TMD patients accounted for 58% of total claim payments. These 13% of TMD patients accounted for $3.85 million of the $5.4 million (71%) of the difference in total payments between cases and controls.

The magnitude of differences in utilization and costs of care between the TMD and non-TMD patients extended over a variety of diagnostic categories. The bulk of the cost differences between the TMD patients and non-TMD patients were attributed to diagnoses or conditions that were not usually considered related to TMD. Among the categories for which inpatient admissions for TMD patients exceeded those of non-TMD patients by a factor of at least 2:1, the most common were: digestive system, mental disorders, circulatory system, injuries/accidents,

respiratory system, musculoskeletal, and nervous system. Differences between TMD and non-TMD populations were also found regarding costs and utilization of drugs, particularly for narcotics, anti-inflammatories, and psychotropics.

The investigators did not annualize the cost findings of the study. Converting these figures to an annual basis, the total payments for all types of claims was $2,973 per TMD patient per year, compared to $1,486 per non-TMD patient per year. Payments for only the four diagnoses most closely identified with TMD amounted to $133 per TMD patient per year. If the payments for claims for the additional 29 TMD-related diagnoses are included along with the original four diagnoses for TMD, then the payments for TMD-related diagnoses increase to $156 per TMD patient per year.

As noted by the investigators, the TMD health benefit for the insurer in this study was new. So, some people with TMD might not have sought care under the health benefit plan or might have received care from a dentist that did not show up in the data. Also, other patients diagnosed with TMD before or after the 1989-1990 study period would not have appeared as TMD patients in this study, since claims paid by other carriers would not have been available for analysis. As noted above, these payments came from a database of an insurer that did not offer dental insurance, and therefore did not capture most care that was provided to these patients by dentists.

b) Study of a large managed care organization, 1994

In a subsequently report, Shimshak and DeFuria (1998) examined 1994 claims data from a New England managed care organization with a large, mixed geographic population. TMD patients were identified using a proprietary diagnosis code grouping methodology comprising 17 ICD-9 codes related to TMD. Out of a total patient population of 534,198, there were 1,713 patients who incurred at least one claim from among these codes in 1994. The remaining 532,485 enrollees, who had no claims in the set of 17 TMD codes, including nearly 40,000 who received no health care services that year, were designated the comparison group for this study. Data for the non-TMD patients were adjusted for age and sex in order to be used as a basis of comparison. The study accounted for inpatient claims, outpatient claims, and psychiatric inpatient and outpatient claims, measured separately.

The magnitude of the differences in utilization and cost of health care services between TMD and non-TMD patients extended over a wide range of diagnostic categories. Except for pregnancy and childbirth, the per capita hospital admissions for TMD patients were higher than those for non-TMD patients for every major diagnostic category with a substantial number of admissions. The inpatient cost per capita for TMD patients was more than 80% higher than for non-TMD patients, i.e., $936 vs. $517. Even when the cost of all TMD-specific claims (i.e., excluding claims in the 17 TMD-related diagnoses) was excluded, the inpatient cost per capita for TMD patients was more than 46% greater than for non-TMD patients, i.e., $753 vs. $517. Similarly, the outpatient cost per capita for TMD patients was twice that for non-TMD patients, i.e., $1,738 vs. $870. When the cost of all TMD-specific claims was excluded, the outpatient costs per capita for TMD patients was 79% greater than for non-TMD patients, i.e., $1,560 vs.

$870. The differences in per capita psychiatric costs, both for inpatient ($35 vs. $16) and outpatient ($64 vs. $38) costs, measured separately from other inpatient and outpatient costs, also varied by a factor of about 2:1. The removal of the nearly 40,000 enrollees who received no health care services during the year had a negligible effect on the magnitude of cost differences between the groups. (The cost figures provided in this study appeared to be in current dollars, not adjusted for inflation.)

Based on the costs reported by the investigators, the total annual inpatient, outpatient, and psychiatric costs were $2,773 per capita for the TMD patients and $1,440 for the non-TMD patients. Of the difference in the groups of $1,333, the amount due to costs associated only with the group of 17 ICD-9 codes related specifically to TMD was $361. Thus, the cost of care for the TMD-specific diagnoses constituted 13% of the total cost of care for TMD patients and 27% of the difference in cost of care between TMD and non-TMD patients. (These summations of total annual per patient costs and differences were not provided in the published article.)

Dental claims were not part of the data set, and it is likely that some enrollees received care from dentists. Other enrollees might have been treated for TMD before or after the 1994 study year, and would not have appeared as TMD patients in this study.

c) Study of a large health maintenance organization, 1990-1995

White et al. (in press) conducted a case-control study of health care utilization and costs involving 8,800 TMD patients who were continuously enrolled members of Kaiser Permanente Northwest during the six-year period 1990-1995. TMD cases were identified as those enrollees who had at least one TMD clinic visit or one TMD-related procedure during the six-year study period. The eligible set of TMD-related procedures included four CPT codes and 18 ICD-9-CM procedure or diagnosis codes. An equal number of control subjects were identified and matched to the cases using 14 variables, including age and sex. The mean age for both groups was 40.5 years, 80% were female, and 70% were between the ages of 20 and 50.

Costs included in the study were outpatient visits (including mental health visits), outpatient pharmaceuticals, radiological services, TMD clinic visits, dental visits, inpatient admissions, and outside claims for outpatient and inpatient services. The investigators separated TMD clinic services from other dental services by identifying a set of procedure codes used only by TMD clinic providers.

TMD patients used more of all types of services than those without TMD. On average, TMD cases had 57% higher costs for all services than did controls, i.e., $15,996 vs. $10,174 (adjusted to 1995 dollars) over the course of the six-year study period. The median costs for TMD cases was 93% higher than the non-TMD controls, i.e., $9,421 for the TMD cases and $4,879 for the non-TMD controls. The investigators did not report the specific costs associated with only the CPT and ICD-9-CM codes used to identify TMD patients.

The differences between TMD patients and non-TMD patients in health care utilization and costs was consistent over a wide range of services. However, these differences were largely attributable to services other than for diagnostic categories closely related to TMD itself. Of the difference in mean costs between the two groups, 39.6% was attributable to outpatient visits, 23.8% to inpatient admissions, 12.1% to outpatient pharmaceuticals, and 7.5% to radiological services. Only 6.8% of the difference was due to TMD clinic visits, and 4.4% to dental visits. Outside claims for outpatient and inpatient services accounted for the remaining 5.8% of the difference in average costs between the two groups.

About 10% of TMD cases and non-TMD controls accounted for 40% and 47% of the costs in each group, respectively. About 30% of patients in each group accounted for more than two-thirds of all costs. The median cost of inpatient care for both groups was zero, as most health plan enrollees are not hospitalized in any six-year period. The median cost of dental care for the TMD cases was $292 (or about $49 per year) and zero for the non-TMD controls. During the six-year study period, TMD patients made an average of 3.26 visits to the TMD clinic. TMD patients also made an average of 7.46 dental visits, compared to 5.28 dental visits by non-TMD controls.

Over the six-year period, the average per patient cost for TMD cases was $2,661, compared to $1,696 for non-TMD controls. Of the difference in the groups of $965, 11.2%, or about $108, was due to TMD clinic visits (6.8%) and additional dental visits (4.4%) by TMD patients. (The determinations of annual per patient costs were not provided by the authors.)

3. Patient Out-of-Pocket Costs

Given that much of the care for TMD is not captured by health plan data sets, per patient out-of-pocket costs are poorly documented. To the extent that various TMD interventions are not covered by insurance, out-of-pocket costs would be expected to comprise a larger proportion of total per-patient costs. The TMJ Association (2000c) has unpublished data from a 1999 survey of TMJ patients known by the association concerning sociodemographic characteristics, insurance status, out-of-pocket costs, and other information. There were 187 respondents out of an unspecified number of people contacted for the survey. Respondents were asked to "Estimate your out-of-pocket costs (not covered by insurance) for TMJ treatments (include medications)." Among the 130 people who responded to this item, reported average out-of-pocket expenditures was $40,160. The average out-of-pocket expenditures for respondents identifying themselves as implant patients and as non-implant patients were $68,371 and $13,642, respectively. However, neither the questionnaire nor the reported results addressed the time period for these expenditures. Reported out-of-pocket costs fell into the $1–$4,999 range for 29% of these respondents, into the $5,000-9,999 range for 10% of respondents, and into the $10,000-$49,999 range for 40% of the respondents. Six respondents reported out-of-pocket expenditures in excess of $200,000, including two in excess of $500,000. These outlier estimates have a sizable effect on the reported average estimate of $40,160. No median estimate was provided.

Although The TMJ Association survey provides some rough information about out-of-patient costs as estimated by a selection of TMD patients, it is subject to various potential biases. Among these are self-selection bias by patients choosing to become members of The TMJ Association, self-selection for high cost experience patients in response to a survey about costs, and respondent recall bias.

A wide range in the magnitude of out-of-pocket costs also was reported in an earlier study by Garro et al. (1994). Based on interviews of 32 members of a TMD support group, self-reported out-of-pocket costs ranged from $35 to $40,000. Half of the subjects reported out-of-pocket costs of $5,000 or more, and more than one-fourth reported costs of $10,000 or more. However, the report did not address the time period over which these expenses were incurred.

The available information concerning out-of-pocket costs for TMD patients is very limited and subject to methodological weaknesses. Nevertheless, it does provide further indication of there being a TMD patient population that has experienced very sizable out-of-pocket costs while pursuing treatment for health conditions that can be painful, debilitating, and intractable.

4. Other Types of Cost Studies

Studies (both published and unpublished) exist that report on health services utilization and costs associated with treating certain subgroups of TMD patients or on particular procedures or protocols for treating certain types of patients in specific settings. However, these reports generally are not representative of the broader TMD population. For example, one study indicated that TMD surgical interventions may result in reduced TMD costs due to a decreased need for health services subsequent to surgery (Moenning et al. 1997). Based on patient self-reported data, TMD patients in that study were found to spend $7 less per month on medications subsequent to orthognathic surgery (to align the jaw) and require fewer physician visits.

As part of a business plan for the purposes of documenting the utility of opening an orofacial pain center, the National Naval Dental Center used a modeling approach to estimate per patient costs for treating orofacial pain. The analysis incorporated specific codes for procedures that would be used to treat patients in this setting. This analysis indicated that the per patient cost for treating patients with orofacial pain in a pain management clinic would be $267 per one hour session for an average of five visits per patient, for a total of $1,335 per patient (Stakeholder interview February 2, 2001). However, the selection of hypothetical patients with orofacial pain likely overlaps, but does not represent well, the TMD populations of other studies. Further, the new pain treatment protocol proposed for these patients is not representative of prevailing treatments of TMD.

5. Payment

The imprecise nature of TMD hinders the ability of payers to identify and make appropriate payment decisions concerning its diagnosis and treatment. Indeed, current coverage patterns for TMD treatments vary widely. In some states coverage is legislatively mandated rather than

being determined by health plans or other health care payers. Many private insurers only partially cover care for TMD, or do not provide coverage at all with benefit packages specifically excluding coverage for it. As a result, out-of-pocket costs for some affected individuals can be substantial, though estimates of the magnitude of these costs among the TMD population are not well documented.

Payers remain concerned that adequate evidence does not exist to demonstrate that many treatments for TMD improve the condition of these patients, and that some treatments may worsen patients' conditions. Many payers who are familiar with the TMD literature are aware that symptoms spontaneously subside in large portions of the TMD patient population, raising questions about the utility of treating across the TMD population and concerns about the potential adverse sequelae of more invasive treatments. Moreover, payers are concerned about the accuracy of tests used to diagnose TMD. Payers report preferring more objective tests for diagnosing TMD, such as radiographic evidence, as opposed to more subjective ones (Payer interview, 2000). Even so, while some payers acknowledge that MRI has utility in demonstrating physiological signs that are sometimes associated with TMD, they are not convinced that there is a clear connection between apparent TMD on MRI and symptoms.

Payers express receiving increased pressure to pay for TMD interventions (Payer interview, 2000). The Health Care Financing Administration (HCFA) allows coverage of surgical procedures for TMD under Medicare, but not non-surgical treatments. As is the case for many types of health care procedures, many large private payers are influenced by the coverage policies of HCFA.

Though some states have mandates to pay for TMD interventions, these typically specify coverage for certain treatments only. According to a compilation of the American Dental Association, the following 19 states have laws, regulations, or directives requiring health insurance policies issued within the state to include coverage for the diagnosis and treatment of TMD: California, Florida, Georgia, Illinois, Kentucky, Maryland, Minnesota, Mississippi, Nevada, New Mexico, North Carolina, North Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin. States typically place some payment bounds on these requirements, e.g., Illinois: maximum lifetime at least $2,500; Mississippi: maximum lifetime at least $5,000; North Carolina: maximum lifetime benefit $3,500; North Dakota: maximum lifetime benefit $10,000 for surgical and $2,500 for non-surgical treatment; and Wisconsin: annual maximum $1,250 (ADA 2000).

As occurs for certain other types of health care interventions, legislative mandates to cover interventions for TMD can circumvent payers' efforts to implement evidence-based coverage policies. Even in the presence of such mandates, the lack of strong evidence and recognized guidelines can lead to legal controversy. Payers have expressed concern that courts have routinely awarded coverage for TMD by health plans, despite exclusionary contract language and evidence that the insured patients have failed to disclose preexisting conditions or seek more conservative treatment first as required (Johnson 1997).

6. Summary of Cost Findings

A comparison of the total per patient costs drawn from the studies by Shimshak et al. (1997), Shimshak and DeFuria (1998), and White et al. (in press) yields a rough convergence. In the Shimshak et al. (1997) study of patients in a large northeastern health insurance plan during 1989-1990, the total annual per patient cost for TMD patients was $2,973 (current dollars), or 100% more than the non-TMD patients. In the Shimshak et al. (1998) study of patients in a large northeastern managed care organization during 1994, the total annual per patient cost for TMD patients was $2,773 (current dollars), or 93% more than the non-TMD patients. In the White et al. (in press) study of patients in a large northwestern HMO during 1990-1995, the total annual per patient cost for TMD patients was $2,661 (1995 dollars), or 57% more than the non-TMD patients.

As noted above, little or none of the costs of services provided by dentists was included in either of the Shimshak et al. (1997) or the Shimshak and DeFuria (1998) studies. The study by White et al. (in press) did account for costs of visits to a special TMD clinic as well as dental visits, which contributed 6.8% and 4.4%, respectively, to the differences in total average costs of the TMD cases and the non-TMD controls. Presumably, in the absence of the TMD clinic, a significant portion of the services provided there would have been absorbed by other types of outpatient, inpatient, or dental visits. Of course, there were certain differences in the criteria used to define TMD subjects in these studies, including the ICD-9-CM codes and, in the case of the White et al. study, the CPT codes and use of the TMD clinic in that study setting. The summary per patient cost figures are shown together in Table 8. Using the Medical Care Consumer Price Index (CPI), these figures are updated to 2000 dollars.

Table 8: Summary of Cost Data from Three Studies

Study	Base Year of Cost Data	Total Annual Per Patient Costs Base Year TMD	Non-TMD	Medical CPI Conversion Base Year–2000	Total Annual Per Patient Costs 2000 TMD	Non-TMD	Diff.
Shimshak et al.	1989-90	2,973	1,486	1.56	4,638	2,318	2,320
Shimshak and DeFuria	1994	2,773	1,440	1.23	3,411	1,771	1,640
White et al.	1995	2,661	1,696	1.18	3,140	2,001	1,139

Therefore, a rough approximation for total annual per patient costs for TMD patients is $3,100 - $4,700. A rough approximation for the difference between total annual per patient costs for TMD and non-TMD patients is $1,100 - $2,300. These estimates do not include out-of-pocket costs.

Rough estimates of the per patient costs of care associated with TMD-related services only, i.e., based on procedure and diagnosis codes generally recognized as being directly related to TMD,

may be inferred from the studies by Shimshak et al. (1997) and Shimshak and DeFuria (1998). As noted above, cost data reported by Shimshak et al. (1997) for the four ICD-9-CM codes used in that study to identify TMD patients can be annualized on a per capita basis, yielding an estimate of $133 per TMD patient per year, or $207 in 2000 dollars. Including the payments for claims for the additional 29 TMD-related codes increases that figure to $156 per TMD patient per year, or $243 in 2000 dollars. Similarly, using data from Shimshak and DeFuria (1998) for the 17 ICD-9-CM related specifically to TMD yields an estimate of $361 per TMD patient per year, or $444 in 2000 dollars. Of course, differences in the sets of codes used to identify TMD patients in these studies are among the multiple factors that likely contribute to differences in the cost estimates. While the estimates from these studies are of the same order of magnitude, they are small compared to the total health care costs generated by TMD patients, and small compared to the differences in total health care costs generated by TMD patients and non-TMD patients. While it does appear that the annualized costs and differences between TMD patient and non-TMD patient costs decrease with the more recent studies (including White et al. [in press]), these differences may be attributable to many factors other than any true cost trends. The few available studies on TMD-related health care costs that have been made available since 1996 do make clear that TMD patients use significantly more health care services than other patients, and that most of the cost of care provided for TMD patients is for diagnoses or conditions that are not known to be directly associated with TMD.

C. Ongoing Research

In considering the state of the TMD literature, it is useful to remain cognizant of ongoing studies that could make important contributions to the evidence base. Four additional ongoing studies relevant to TMD, including some identified by a search of the NLM's Clinicaltrials.gov database, are noted below. The latter three of these studies is still recruiting patients.

1. Alternative Treatments for TMD

A current RCT for which a report has not been published to date may offer further insights regarding the relative effectiveness of treatments for TMD with varying levels of invasiveness. Preliminary results of the trial, being conducted at the University of Minnesota, were presented by Dr. Eric L. Schiffman at the Temporomandibular Interagency Working Group Meeting held at the NIH/NIDCR on December 1, 2000 (Schiffman 2000, December). In this ongoing investigation, Schiffman et al. are studying 96 patients who were diagnosed with disc displacement without reduction, pain, and limited mouth opening. These patients were randomized into one of four treatment groups: medical management with standard pain medication (also including patient education, thermotherapy, rest, and monitoring), nonsurgical rehabilitation (including medical management plus orthodontics, dental visits, physical therapy, and health psychology), arthroscopic surgery (including nonsurgical rehabilitation), and disc repositioning surgery (including nonsurgical rehabilitation). There is no non-intervention control group included in this trial. Data are being collected at three-to-six month intervals with an objective measure of jaw function (mandibular movement and noise, using the Craniomandibular

Index [CI]) and a subjective perception of pain (using the Symptom Severity Index [SSI-JT]), and patients are being followed for five years.

Preliminary findings indicate that, after three months, all four groups improved relative to baseline for the CI and SSI-JT, but that there was no statistically significant difference among the groups. All patients have been in the study for at least two years, with more than half of all patients followed for at least five years, and the projected loss-to-follow-up rate is 15% at five years. To date, this study has had significant patient crossover, with approximately 40% of the study subjects crossing over from the medical management group to the nonsurgical intervention group during the course of the investigation. Also reported were preliminary estimates for direct costs of treatment, including medical management: $1,385; nonsurgical rehabilitation: $2,379; arthroscopic surgery: $7,890; and disc repositioning surgery: $13,128. These estimates were for costs to date for patients who had been enrolled in the trial for at least two years. Investigators suggest that five-year results will not be adequate for assessing the lifetime effectiveness of these treatments, and that a longer follow-up period is warranted. It is stressed that information shared at the December 2000 briefing was of an interim, preliminary nature only, and may not be consistent with the final results of this trial, which are not expected to be reported until 2003.

2. *Study of Etanercept and Celecoxib to Treat Temporomandibular Disorders (Painful Joint Conditions)*

This NIDCR-sponsored, two-part RCT will concurrently evaluate the effectiveness and side effects of two new anti-inflammatory drugs for relieving pain and improving jaw function in patients with TMD. Part 1 will evaluate celecoxib (Celebrex) and Part 2 will evaluate etanercept (Enbrel). Participants will complete written questionnaires about their jaw condition and will undergo a medical history, complete TMD evaluation, blood and urine tests, and radiographic and MRI studies of the TMJ. In both parts of the study, patients will be randomly assigned to either a treatment group or a placebo group. All patients will have a final evaluation six weeks after beginning treatment, including a TMD physical examination, and laboratory and x-ray tests as required. Pain diaries and questionnaires will be collected at the final visit. Decrease in pain, dysfunction, and improvement in quality of life will be assessed at base line and at the 6-week follow-up in the celecoxib study. In the etanercept study, individual outcomes, such as pain, mandibular range of motion, and an analysis of sample synovial fluid level of TNF (tissue necrosis factor) alpha will be assessed at baseline and at the six-week follow up.

3. *Complementary Medicine Approaches to TMD Pain Management*

This Phase II clinical trial, sponsored by the National Center for Complementary and Alternative Medicine (NCCAM), will evaluate whether selected complementary approaches to TMD pain management (i.e., acupuncture, chiropractic therapy, and bodywork therapy) delivered by complementary practitioners is as effective as usual TMD care provided by clinicians in a TMD clinic. Subjects will be evaluated at baseline, and six and 12 months post-intervention. Clinical examinations, saliva samples to assess salivary cortisol levels, and a series of questionnaires to

assess pain and grade of dysfunctional pain, psychological functioning, and other physical symptoms will be used to assess outcomes. The investigators will passively monitor health care utilization within Kaiser Permanente Northwest using clinical, research, and administrative databases. If these complementary interventions are shown to be effective, the goal is to design and implement a Phase III clinical trial to further evaluate the health consequences and cost of these therapies.

4. Alternative Medicine Approaches for Women with TMD

In another sponsored by the NCCAM, researchers are proposing to holistically address patient symptoms through three different approaches: naturopathic medicine (NM), traditional Chinese medicine (TCM), and usual care at Kaiser Permanente Northwest to better account for the multifactorial nature of TMD. The study will include a pilot test and Phase II trial to evaluate the two alternative healing approaches, TCM and NM delivered by TCM and NM practitioners, to compare the effectiveness of these approaches with usual TMD care provided by dental clinicians in a TMD Clinic. Subjects will be females with multiple health problems (defined as patients who have had at least four organ system-grouped diagnoses in the past year, not including TMD). Evaluations will be made at baseline, six, and 12 months after start of treatment. The primary endpoint will be change from baseline in the Axis II Pain Related Disability and Psychological Status Scale. Clinical examinations, saliva samples to assess salivary cortisol levels, and responses to a series of questionnaires to assess pain, chronic pain, psychosocial functioning, and other physical symptoms will be used to assess outcomes. The investigators will passively monitor health care utilization within Kaiser Permanente Northwest using clinical, research, and administrative databases to determine whether the interventions have an impact on overall health care utilization. To the extent that either of these alternative interventions is shown to merit a Phase III trial, the goal is to design and implement such a clinical trial to further evaluate the health consequences and costs of these alternative healing paradigms.

XII.DISCUSSION

TMD encompasses a variety of clinical disorders involving the TMJ, the muscles of mastication, and contiguous tissues. No clear consensus has emerged regarding the definition of TMD, its causes, how to diagnose it, most useful outcome measures, or how best to treat it. Multiple unrelated, underlying diseases can cause TMD symptoms, although no specific cause can be identified in many patients. Understanding of TMD etiology is complicated by multiple risk factors that are poorly documented or understood. The natural history of the condition is not well understood. TMD symptoms can increase and abate over time, and can resolve spontaneously without serious long-term effects.

The breadth of signs and symptoms of TMD and inconsistent information about TMD within the clinical communities often confounds diagnosis. Moreover, there is no widely accepted, standard test currently available to identify TMD. What diagnostic criteria that do exist are not well integrated into standard clinical practice. The ambiguity in TMD diagnosis contributes to

the use of a variety of diagnostic procedures and their attendant costs, as well as frustration for many patients.

Insufficient understanding of the etiology and course of TMD, along with insufficient diagnostic criteria, confound determination of effective treatments. Without adequate understanding of TMD, including its varying underlying causes in different subgroups of TMD patients, it is more difficult to demonstrate the effect of TMD interventions. To the extent that any treatment for a particular type or subgroup of TMD patients may be truly effective, measurement of its treatment effect in a clinical trial may be masked by the treatment's lack of effectiveness for other types of TMD patients included in such a trial.

Caring for TMD patients is further complicated by the range of clinicians involved in treating those afflicted with TMD. Selection of treatment appears to be associated with the type of provider consulted, underlining the lack of consensus regarding appropriate clinical expertise for managing TMD, and potentially facilitating vested interests among providers in particular treatments. In reference to a large portion of TMD patients, this is captured by Chase (2000), as follows.

> *What currently happens to patients seeking care for chronic TMD orofacial pain disorders? They become part of the diagnostic and treatment expertise of the general dentist, dental specialists, orofacial pain centers, and part of many other medical specialties, including both physician and nonphysician care. The care they receive is dependent on the health care door they walk through. The dentist may provide a splint, the chiropractor may provide manipulation, myofascial therapy, nutritional therapy, or even splint therapy. The neurologist will provide medications, the physical therapist will provide iontophoresis or other physical medicine modalities, otolaryngologists may provide splints or medication, massage therapists may provide deep tissue massage or cranio-sacral therapy, and the psychologist may provide biofeedback training, yoga training, or cognitive therapy. Any or all of these therapies may give the chronic pain patient a level of relief, and many of them are less expensive than care dispensed by dentists.*

A consequence of the uncertain and diverse clinical responsibility for TMD management, many patients endure extended searches for a definitive diagnosis and effective treatment, resulting in higher costs and exposing them to potentially adverse treatment effects.

The potential adverse effects of any treatment for TMD must be weighed against any relative benefits that it might confer relative to other TMD treatments, or to no treatment at all. Some treatments, including certain forms of the more invasive treatments, can result in greater pain, disfigurement, and other adverse effects. Given the lack of definitive evidence for the superiority of particular treatments for most TMD patients, more clinicians and researchers argue for employing conservative, reversible approaches to managing most patients with TMD, and progressing to increasingly more invasive ones only upon failure of the more conservative, reversible ones.

The body of evidence on the effectiveness of TMD treatment is generally limited and lacking in rigor. Our findings reinforce previous conclusions that few RCTs, particularly ones large enough to detect any true differences in outcomes among alternative treatments, or other types of rigorous studies exist for determining the effectiveness of treatments for TMD. The 45 studies that met our selection criteria exhibited a largely bi-modal distribution, including 15 RCTs and 20 single case studies/anecdotes. The design, implementation, and interpretation of clinical trials of TMD treatments is compromised by the absence of sufficient understanding of the etiology and course of TMD and diagnostic criteria that could be used for staging or other clinically meaningful distinctions among subgroups of TMD patients. Particularly lacking is evidence demonstrating relative differences in effectiveness among these treatments. Many of the existing clinical studies indicate that patients improve following treatment; however, few studies include non-intervention or placebo groups designed to control for such confounding phenomena as the placebo effect, regression to the mean, spontaneous abatement of symptoms, or cyclical expression of the disorder known to occur in TMD.

This current ambiguity in diagnosis and treatment of TMD patients is compounded by the fact that the literature in this area cannot be easily summarized, making it difficult to integrate findings from multiple studies. Many instances exist where a body of evidence on the effects of a health care intervention on certain diseases or conditions comprises conflicting findings or inconclusive findings due to studies having sample sizes that are too small for detecting true treatment effects. In these cases, it may be possible to integrate findings using meta-analysis or other integration approaches. However, these usually require having a group of studies involving a particular intervention used in populations with same or similar indications. The lack of clearly defined diagnostic criteria and well-defined interventions compromises efforts to integrate results from multiple studies or otherwise draw inferences about the effectiveness or cost of TMD treatments.

The potential discrepancy between the more "ideal" conditions in some RCTs and other investigations of TMD treatments conducted in research settings and the conditions of routine clinical settings in which most TMD is managed may diminish the validity of some of the available literature. This is recognized by researchers and was emphasized by certain of our clinician interviewees. RCTs conducted under ideal conditions and lacking sufficient duration may not add greatly to understanding "real-world" care, which often involve long-term treatment utilizing combinations of therapies and flexible pharmaceutical dosages. While this is a common debate in clinical research, it may be more relevant in this case due to the heterogeneous nature of TMD cases and treatments.

Our literature review confirms earlier efforts that there is a paucity of high-quality research available to eliminate some of the uncertainty surrounding diagnosis, treatment and measurement of outcomes for TMD patients. From an initial list of 840 articles identified related to TMD since 1996, only 45 studies were specific to treatment of TMD, and only five articles described the cost treating TMD. Of the 15 articles reporting evidence from RCTs of treatment for TMD, eight found significant improvements in pain and/or function from study initiation through follow-up. However, as noted above, most of these studies did not include a non-treatment control group, raising questions about the extent to which improvements could be attributed to

treatments. The largest type of literature published is classified as a single case study or anecdote, and the literature is diffuse in terms of modality explored. As a result, the literature on any one type or even group of interventions is limited, and it is difficult to draw well-founded conclusions about how well interventions for TMD work.

From the research on behavior modification and physical therapy, studies suggest that some types of interventions can be helpful in reducing pain and increasing function. Unfortunately, interventions studied range from a physical self-regulation to posture correction to an ambiguously described "cognitive therapy." The inclusion of long-term follow-up data, non-treatment comparison groups, and a comparison of the different methods of behavioral modification and physical therapy could improve the evidence on this category of treatment.

None of the published studies of pharmaceutical management for TMD identified since 1996 indicated significant, positive results.

Studies of occlusal therapy produced mixed results. Each of the four reports of RCTs involved a different occlusal appliance, thus complicating the ability to for consensus about a specific course of treatment. Overall occlusal therapy appears to have positive outcomes in the short term, though the improvement was not always statistically significantly different from the comparison group.

Two of the three RCTs that examined surgery as an option compared arthroscopy to arthrocentesis without including a non-treatment group. Both studies found improvement in pain and functioning and were not significantly different from each other, though arthroscopy may have better pain outcomes. The third RCT compared different arthroscopy techniques and found positive results over a one-year period. The non-RCT literature on surgery suggests that this option should be considered after other treatment methods have been attempted; in four of the 10 studies, patients had more pain and worse functioning following surgical intervention.

The useful recent literature on the cost of TMD is limited to a handful of retrospective studies, including two large case control studies and one large cohort study with a contemporaneous control group. Nevertheless, these are useful studies.

Using the findings of the studies as well as other determinations based on the results presented in them, a rough approximation for total annual per patient costs for TMD patients is $3,100 - $4,700. A rough approximation for the difference between total annual per patient costs for TMD and non-TMD patients is $1,100 - $2,300.

The limited literature on cost is consistent in two main ways. First, TMD patients use significantly more health care services and generate more costs than non-TMD patients. Second, perhaps contrary to expectation, most of the care used by TMD patients is not directly related to conditions generally recognized to be associated with TMD itself. Together, these observations lend further support to the observations that a significant portion of patients with TMD have other health problems, and that in many patients, TMD may itself be a symptom or other

manifestation of one or more other health problems associated with, e.g., the musculoskeletal system, digestive system, mental health, or nervous system.

Among the major findings of the recent report of the Surgeon General on oral health in America (U.S. Department of Health and Human Services 2000), there were two that were in particular accord with this study, excerpted as follows.

> ***More information is needed to improve America's oral health and eliminate health disparities*** *.... Health services research, which could provide much needed information on the cost, cost-effectiveness, and outcomes of treatment, is also sorely lacking ....*
>
> ***Scientific research is key to further reduction in the burden of diseases and disorders that affect the face, mouth, and teeth.*** *The science base for dental diseases is broad and provides a strong foundation for further improvements in prevention; for other craniofacial and oral health conditions the base has not yet reached the same level of maturity ....*

In the current era of evidence-based health care, the body of evidence on TMD treatment remains largely weak and unfocused. This contributes to ambiguity and variation in patient care for TMD. The limited data on per-patient costs of TMD make it difficult to assess the cost of managing the disorder and its broader economic impact. It is apparent that the additional health care costs generated by patients with TMD are for procedures and services that are not generally recognized as being directly related to TMD. The limited evidence on the efficacy/effectiveness of TMD treatment and per-patient costs likely contributes to reluctance of third-party payers to cover TMD treatment and variation in payment patterns among those that do provide coverage. There is growing recognition in the dental profession of the importance of evidence in guiding clinical and payment decisions (Marbach and Raphael 1997); however, this remains to be reflected sufficiently in the body of evidence pertaining to management of TMD.

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XIV.APPENDIX A: EFFICACY AND EFFECTIVENESS LITERATURE

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Randomized Controlled Trial	Physical self-regulation training for the management of temporomandibular disorders.	Carlson CR, Bertrand PM, Ehrlich AD, Maxwell AW, Burton RG	In press: Journal of Orofacial Pain	Behavior/ Physical Therapy *(Physical self-regulation; breathing, posture, proprioceptive re-education)*	44	3 w	At 6 w and at 26 w	Single	For both groups, life interference from pain improved ($p<0.001$), perception of control ($p<0.001$), opening without pain ($p<0.05$).	Treatment group reported less pain ($p<0.04$), greater incisal opening ($p<0.04$ w/pain; $p<0.01$ w/o pain) than the control group	10 males/34 females; mean age 35 y; mean duration of pain 52.3 months; patients all had myofacial pain	Visual Analog Scale (VAS) and New Haven-Yale Multidimensional Pain Inventory (MPI) pain; psychological measures (SCL-90R)	Findings support the use of physical self-regulation for the short- and long-term management of pain in the facial region.
	The pattern of splint usage in the management of two common temporomandibular disorders. Part I: The anterior repositioning splint in the treatment of disc displacement with reduction.	Davies SJ, Gray RJ	Br Dent J 1997; 183(8):199-203	Occlusion (*Splint usage to treat clicking and treatment of disc positioning*)	70	12 w	At 3 years (not yet published)	No	Yes, but values from baseline not reported.	The group wearing a splint for 24 hrs/day improved significantly over those wearing it only during the day or only at night ($p<0.05$).	15 males/55 females; age range 15-70 (mean 31y); duration of complaint 15-72 m (mean 44 m); patients with TMJ disc displacement w/ reduction	Clicking; subjective assessment of pain	Splints were shown to be appropriate for treatment of disc displacement with reduction though patients should wear the splint 24 hrs a day.
	The pattern of splint usage in the management of two common temporomandibular disorders. Part II: The stabilisation splint in the treatment of pain dysfunction syndrome.	Davies SJ, Gray RJ	Br Dent J 1997; 183(7):247-51	Occlusion (*Splint usage to treat pain*)	70	12 w	At 3 years (not yet published)	No	Not reported.	No statistical difference between groups.	9 males/61 females; age range 14-61 (mean 33y); patients with pain dysfunction syndrome	Degree of jaw opening; joint sounds; subjective assessment of pain	Patients treating TMD pain with a stabilization splint need wear the splint only at night.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Randomized Controlled Trial (continued)	Triazolam improves sleep but fails to alter pain in TMD patients.	DeNucci DJ, Sobiski C, Dionne RA	J Orofac Pain 1998; 12(2):116-23	Pharmaceutical Management (*Triazolam*)	20	2 w	No	Double	Yes, but values from baseline not reported.	Treatment group reported significant improvement in sleep quality ($p<0.05$) and time in Stage-2 sleep, but no significant difference was found between groups for pain.	1 male/18 females; age range 24-55 (mean age 39 y); mean duration of TMD pain 9.5 y; all patients diagnosed with painful TMD involving the muscles of mastication and/or the TMJ	Subjective report of sleep quality; duration in stage-2 sleep; subjective assessment of pain; facial muscle electromyographic activity	This study failed to support the hypothesized relationship between sleep disturbances and chronic orofacial pain.
	Diclofenac sodium as an alternative treatment of temporomandibular joint pain.	Ekberg EC, Kopp S, Akerman S	Acta Odontol Scand 1998; 54(3):154-9	Pharmaceutical Management (*Diclofenac sodium*)	32	2 w	No	Double	Treatment group reported significant reduction in pain ($p<0.05$) at the third exam).	Only significant difference between groups was for one data point (tenderness at first exam, $p<0.05$), though this diminished at later exams.	5 males/27 females; age range 27-82 (mean 47y); duration of complaint 17 m (mean); patients with localized TMJ pain	VAS pain, masticatory sensitivity, mandibular mobility	No evidence to show that diclofenac should be used as a primary treatment for TMD pain, but it could be used as a complement to other treatments of acute TMD pain.
	Occlusal appliance therapy in patients with temporomandibular disorders. A double-blind controlled study in a short-term perspective.	Ekberg EC, Vallon D, Nilner M	Acta Odontol Scand 1998; 56(2):122-8	Occlusion (*Occlusal appliance therapy*)	60	10 w	No	Double	Both groups improved overall for subjective symptoms ($p<0.001$), for worst TMJ pain ($p=0.001$ treatment; $p=0.0034$ control), and for pain ($p=0.0001$ treatment; $p=0.003$ control).	The treatment group showed significant improvement over the control group for overall symptoms ($p=0.06$) and frequency of daily pain ($p=0.02$).	5 males/53 females; age range 13-76 (mean 30y); none had received previous TMD treatment; patients with TMD of arthrogenous origin	Subjective assessment of pain; frequency of daily or constant pain	Both the stabilization appliance and a control appliance reduced TMJ pain from baseline, though there was no significant difference between groups.

	Title	Author(s)	Citation	Treatment Category (specific treatment)	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Randomized Controlled Trial (continued)	Prospective comparison of arthroscopy and arthrocentesis for temporomandibular joint disorders.	Fridrich KL, Wise JM, Zeitler DL	J Oral Maxillofac Surg. 1996; 54(7):816-20; discussion 821.	Surgery (*Arthroscopy and arthrocentesis*)	19	NA	At 1 week, and 1, 3, 4, 12, and 26 months after surgery	No	Report "success rates" of 82% for the arthroscopy group and 75% for arthrocentesis.	No significant difference reported between groups.	19 females; mean age 31 yo; all had internal derangement	VAS pain; maximal incisal opening; deviation of mouth opening or closing; tenderness on palpation	Therapeutic success was not significantly different for arthroscopy and arthrocentesis.
	Improvement of pain and function after arthroscopy and arthrocentesis of the temporomandibular joint: a comparative study.	Goudot P, Jaquinet AR, Hugonnet S, Haeliger W, Richter M	J Cranio-maxillofac Surg. 2000; 28(1):39-43	Surgery (*Arthroscopy and arthrocentesis*)	62	NA	At 1 year after surgery	No	For arthroscopy, improvement in function reported ($p<0.0001$) and pain ($p<0.0001$). For arthrocentesis, improvement in function reported ($p<0.0001$) and pain ($p<0.0001$).	Improvement in mouth opening was significantly better for the arthroscopy group ($p<0.0005$). No statistical difference was found between groups for pain improvement.	75% female; age range 16-72 (mean age 38 y); all had pain in the TMJ area; all had not responded to noninvasive treatment	Functional result and diminishing pain (VAS)	Arthroscopy showed better results for functional treatment; arthroscopy and arthrocentesis show similar results for pain control.
	Posture correction as part of behavioural therapy in treatment of myofascial pain with limited opening.	Komiyama O, Kawara M, Arai M, Asano T, Kobayashi K	J Oral Rehabil. 1999; 26(5):428-35	Behavior/ Physical Therapy (*Posture correction*)	51	52 w	Patients evaluated once a month for 12 months	No	Treatment 2 group improved in pain-free unassisted mouth opening at one month ($p<0.05$), treatment 1 group reached this point at 2 months ($p<0.05$), and the control group reached this point at 6 months ($p<0.05$).	The treatment groups had significantly greater improvements in pain free unassisted opening at 1 month ($p<0.01$), but no difference at any other point. No statistical difference was found between any of the groups at 12 months.	81% female; mean age 25; 93% completed high school; 84% in pain greater than 3 months; patients with myofascial pain and limited mouth opening	VAS pain intensity at maximum mouth opening; disturbance of daily life	Both treatment groups improved from baseline, but there was no significant difference between groups. Posture correction did not do better than no treatment.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Randomized Controlled Trial (continued)	Therapeutic jaw exercises and interocclusal appliance therapy. A comparison between two common treatments of temporomandibular disorders.	Magnusson T, Syren M	Swed Dent J. 1999; 23(1):27-37	Occlusion (*Occlusal appliance therapy*)	26	24 w	At 4 years	No	No baseline analysis was conducted.	No statistical analysis was conducted.	Not stated.	Helkimo scale; behavior rating scale	No difference was found between groups in treatment success, but no statistical analysis was conducted.
	Arthroscopic surgery of the temporomandibular joint: comparison of two successful techniques.	Miyamoto H, Sakashita H, Miyata M, Goss AN	Br J Oral Maxillofac Surg. 1999; 37(5):397-400	Surgery (*Arthroscopic surgery*)	101	NA	52 w	No	Both groups showed significant improvement from baseline for maximal incisal opening at all examinations ($p<0.001$).	Only significant difference between groups was at one month for mouth opening ($p<0.01$).	Mean age 28 y; all were stage III or above for TMJ internal derangement and had not responded to 3 months of non-surgical treatment	VAS pain; range of movements; diet; radiography; complications (if develop)	Recommend that unless early wide mouth-opening is required, the less invasive procedure of lysis and lavage should be chosen over surgery.
	Temporomandibular joint iontophoresis: a double-blind randomized clinical trial.	Schiffman EL, Braun BL, Lindgren BR	J Orofac Pain. 1996; 10(2):157-65	Pharmaceutical Management (*Iontophoresis of dexamethasone sodium phosphate and lidocaine hydrochloride*)	27	Pre and post treat-ment	No	Double	A significant improvement was noted for the treatment group in the Dysfunction Index score ($p<0.01$).	Treatment group reported significantly improved TMJ functionalality ($p=.04$); no other significant differences were found.	5 males/15 females; age range 16-81 (mean 45y); patients with diagnosis of TMJ capsulitis and disc displacement without reduction	Helkimo's Anamnestic Dysfunction Index; the Symptom Severity Index (SSI); maximal active mandibular opening; lateral excursion	Iontophoretic delivery of dexametha-sone and lidocaine improved mandibular function, but did not reduce pain.
	Effect of indomethacin phonophoresis on the relief of temporomandibular joint pain.	Shin SM, Choi JK	Cranio. 1997; 15(4):345-8.	Pharmaceutical Management (*Indomethacin phonophoresis*)	20	Pre and post treat-ment	No	Double	An improvement was reported for TMJ pain sensitivity in the Indomethacin group ($p<0.005$).	No statistical difference between groups.	3 males/24 females; mean age 22; mean Body Mass Index 21; patients had TMJ pain and tenderness upon palpation	VAS and pressure pain threshold pain levels and pain sensitivity	Indomethacin phonophoresis provides pain relief of TMJ pain baseline compared to post-treatment.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Randomized Controlled Trial (continued)	Dysfunctional patients with temporomandibular disorders: evaluating the efficacy of a tailored treatment protocol.	Turk DC, Rudy TE, Kubinski JA, Zaki HS, Greco CM	J Consult Clin Psychol. 1996; 64(1):139-46	Behavior/ Physical Therapy *(Tailored treatment protocol)*	41	Pre and post treat-ment	At 6 months	No	Both groups showed statistically significant improvement from baseline in several physical, psychosocial, and behavioral measures.	The cognitive therapy group showed significantly better outcomes for pain, depression, and medication use.	90% female; mean age 34; 92% high school graduate; 68% married; mean duration of pain 4.2 y; all patients had TMJ pain and limited opening for 3 months or more, no evidence of serious psychopathy, no history of TMJ surgeries, and were at least 18 yo	Exam based on Research Diagnostic Criteria; McGill Pain Question-naire; Beck Depression Inventory; Multidimen-sional pain inventory (MPI); Oral Parafunctional Habits Scale	Cognitive therapy added to a tailored treatment regimen yielded significantly better results than did a regimen without cognitive therapy.
	Usefulness of posture training for patients with temporomandibular disorders.	Wright EF, Domenech MA, Fischer JR Jr	J Am Dent Assoc. 2000; 131(2):202-10	Behavior/ Physical Therapy *(Posture training)*	60	4 w	No	Single	Within the treatment group, significant correlations were found between improvement in TMD symptoms and neck symptoms ($p<0.005$).	The treatment group was found to have significantly greater pain free mouth opening than the control group ($p<0.05$).	9 males/51 females; age range 18-60 (mean 32 y); patients had TMD for at least 6 months; pain was of masticatory muscular origin	Modified symptom severity; maximum pain-free opening; pressure algometer threshold; subjective assessment of pain	Posture training plus TMD self-management may be more effective than TMD self-management alone for patients with a primary muscular disorder.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Non-randomized trial with concurrent controls	Low level laser therapy in the treatment of temporomandibular disorders (TMD): A double-blind pilot study	Conti PC	Cranio 1997; 15(2):144-9	Behavior/ Physical Therapy *(Low level laser therapy)*	20	3 w	No	Double	Significant improvement from baseline was seen in all groups. Treatment resulted in improvement in pain symptoms in myogenous pain patients ($p \leq 0.02$), and improvement in total vertical opening in arthrogenous pain patients.	No statistical difference between groups.	90% female; mean age 40; all patients had pain of either myogenous or arthrogenous origin	VAS pain; mandibular function (active range of motion)	This study found no significant different between treatment and placebo groups.
	Efficacy of arthroscopic surgery and midlaser treatments for chronic temporomandibular joint articular disc derangement following motor vehicle accident.	McNamara DC, Rosenberg I, Jackson PA, Hogben J	Aust Dent J. 1998; 41(6):3 77-87	Surgery (*Arthroscopic surgery and midlaser treatments*)	20	52 w (non-surgery treatment)/12 w (surgery treat-ment)	At 3 years	No	Midlaser with TMJ/occlusal stabilization improved symptoms in both groups ($p<0.01$).	A statistical difference was found between groups for clinical dysfunction index and articular disc derangement at one session ($p<0.01$ for both endpoints); no long-term significance was found.	85% female, mean age 33; disc derangement from motor vehicle accident	Pain-discomfort; Clinical Dysfunction Index; disc derangement; maximal voluntary jaw opening	Conservative management reduced pain, arthroscopic surgery reduced disc derangement, and midlaser treatment with occlusal stabilization improved both.

	Title	Author(s)	Citation	Treatment Category (specific treatment)	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Case control or adjusted cohort study	Temporomandibular disorder: efficacy of an oral habit reversal treatment program	Gramling SE, Neblett J, Grayson R, Townsend D	J Behav Ther Exp Psychiatry. 1996; 27(3):245-55	Behavior/ Physical Therapy (*Habit reversal treatment*)	16	24 w	No	No	Significant improvement from baseline was reported for both group for a number of outcomes.	Treatment group improved significantly compared to the control for facial pain locations (p=0.010), peak intensity locations (p=0.065), weekly pain rating (p=0.033), and the Multidimen-sional pain index (p=0.02).	Mean age 41 y; mean education 15; mean years in pain 6; all patients diagnosed with facial pain	Pain and psychological functioning	Findings suggest that habit reversal training may provide an efficacious and cost-effective intervention for facial pain patients.
Case Series	Intra-articular injection of hyaluronic acid reduces total amounts of leukotriene C4, 6-keto-prostaglandin F1alpha, prostaglandin F2alpha and interleukin-1beta in synovial fluid of patients with internal derangement in disorders of the temporomandibular joint	Hirota W	Br J Oral Maxillofac Surg. 1998; 36(1):35-8	Surgery (*Injection of hyaluronic acid*)	15	2 w	No		Treatment significantly reduced the mean pain score (p<0.01), the noise score (p<0.05), and the degree of mouth opening (p<0.01).	This study did not include a control group.	4 males/11 females; age range 17-64 (mean age 33 y); all patients had unilateral internal derangement of the TMJ without radiological evidence of condylar degeneration	Pain; noise (clicking); degree of mouth opening possible without pain	Inflammation may play a role in internal derangement of the TMJ, and injection of an anti-inflammatory substance may be beneficial to patients with internal derangement of the TMJ.
Single case study or anecdote	Case Report KY: Functional analysis of a follow-up chin cup patient with TMJ pain	Deguchi T, Uematsu S, Mimura H	Angle Orthod 1998; 68(5):425-30	Occlusion (*Occlusal splint*)	1	~520 w (10 years)	No	No	No statistical analyses reported.	No statistical analyses reported.	Female; 10 to 20 yo; presence of anterior crossbite	Pain; jaw position	Splint therapy relieved TMJ pain and helped achieve more normal mandibular movement in this study.
	Phase II therapy for a chronic pain patient: a clinical report.	Dylina TJ	Cranio 1999; 17(2):126-31	Occlusion (*Occlusal therapy*)	1	~12 w	At 3 years	No	No statistical analyses reported.	No statistical analyses reported.	Female; 48 yo; intense facial joint pain and headaches	Subjective assessment of pain	Patient was pain free at 3 years.

	Title	Author(s)	Citation	Treatment Category (specific treatment)	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Single case study or anecdote (continued)	Clinical and experimental study of TMJ distraction: preliminary results.	Festa F, Galluccio G	Cranio 1998; 16(1):26-34	Occlusion (*Physiotherapy and appliance*)	2	20 w (Pt#1); 2 w (Pt#2)	No	No	No statistical analyses reported.	No statistical analyses reported.	(Pt#1) female; 20 yo; jaw lock, pain, limited opening; (Pt#2) female 33 yo; locking; mandible shift	No outcomes reported	No outcomes reported; preliminary report only
	The hypomobile temporomandibular joint.	Friedman MH	Gen Dent. 1997; 45(3):282-5	Behavior/ Physical Therapy (*TMJ manipulation and exercise*)	1	~6 w	No	No	No statistical analyses reported.	No statistical analyses reported.	Male, 71 yo; trismus; limited jaw opening	Jaw opening; pain	The treatment produced lateral pterygoid muscle relaxation at full length, aiding in the restoration of pain-free opening.
	Case report: Treatment for a patient with a history of TMJ disorder.	Grubbs J	Angle Orthod 1999; 69(3):210-3	Surgery (*Occlusal splint; osteotomy; post-surgical treatment*)	1	~32 w	No	No	No statistical analyses reported.	No statistical analyses reported.	Female, 24 yo; patient "wanted" teeth to be aligned"	Maxillo-mandibular relationship	After surgery, patient had "problematic" post-treatment management; she suffered from myolacial discomfort (the patient did not complain of pain before the treatment)
	Worsening of pre-existing TMJ dysfunction following sagittal split osteotomy: a study of three cases.	Hori M, Okaue M, Hasegawa M, Harada D, Kamogawa D, Matsumoto M, Tanaka H	J Oral Sci. 1999; 41(3):133-9	Surgery (*Orthodontic treatment (pre-surgical) and sagittal split osteotomy*)	3	36 w (Pt#1); 24 w (Pt#2); 12 w (Pt#3)	At 9 months (Pt#1); at 3 months (Pt#2); at 6 months (Pt#3)	No	No statistical analyses reported.	No statistical analyses reported.	(Pt#1) female 15 yo; malocclusion; mandibular protrusion; (Pt#2) male 21 yo; malocclusion; mandibular protrusion; (Pt#3) male 28 yo; chronic slight but frequent pain.	Mandibular movement; occlusion; pain; mouth opening	All patients' conditions worsened after sagittal split osteotomy surgery.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Single case study or anecdote (continued)	Passive motion therapy in temporomandibular disorders: the use of a new hydraulic device and case reports.	Horrell BM, Vogel LD, Israel HA	Compend Contin Educ Dent 1997; 18(1):73-6, 78, 80 passim; quiz 86	Behavior/ Physical Therapy (*Passive motion therapy*)	2	14+ w (Pt#1); 12 w (Pt#2)	Pt#1 at 2y; Pt#2 at 1 y	No	No statistical analyses reported.	No statistical analyses reported.	(Pt#1) male, 2.5 yo; gunshot wound to face; (Pt#2) female 14 yo; limited jaw opening; pain; clicking	Mouth opening	Passive motion therapy was successfully used in these cases for rehabilitation of TMJ function.
	The interdisciplinary approach to oral, facial and head pain.	Israel HA, Scrivani SJ	J Am Dent Assoc 2000; 131(7):919-26	Surgery (*Conservative management; arthroscopy; arthroplasty/ discoplasty with discal repositioning; psychiatric counseling*)	1	~52 w	At 2 years (due to complication)	No	No statistical analyses reported.	No statistical analyses reported.	Female, 30 yo; jaw joint pain, headaches, jaw locking – had previously been in a motor vehicle accident	Pain; jaw opening	Case demonstrates physiological pathology complicated by psychiatric disease.
	Surgical orthodontic treatment of skeletal Class III malocclusion with anterior disc displacement without reduction (ADNR): a case report.	Itoh S, Nagata H, Murakami S, Ogura T, Nakagawa K, Takada K	Clin Orthod Res. 1999; 2(4):209-15	Surgery (*Occlusal splint; arthroscopic irrigation; orthodontic surgery*)	1	8 w	Monitored over 5 year period.	No	No statistical analyses reported.	No statistical analyses reported.	Female, 16 yo; skeletal problems; TMJ derangement	Facial esthetics; proper occlusion; "TMD symptoms"	The patient obtained stable facial esthetics and occlusion devoid of TMD symptoms.
	Long-term stability of mandibular orthopedic repositioning.	Joondeph DR	Angle Orthod 1999; 69(3):201-9	Occlusion (*Occlusal splint*)	1	64 w	At 3 years and at 7 years	No	No statistical analyses reported.	No statistical analyses reported.	Female, 26 yo; joint pain; intermittent locking	Jaw position	Complete relapse of the orthodontic treatment took place over time.
	Treatment of temporomandibular joint dysfunction with a visible light-cured resin overlay denture: a case report.	Keng SB	Quintessence Int 1996; 27(2):105-9	Occlusion (*Occlusal splint and dentures*)	1	104 w	At 2 years	No	No statistical analyses reported.	No statistical analyses reported.	Female, 40 yo; overclosure of mandible; clicking; pain	Jaw position; occlusal wear	Overlay partial denture technique may be appropriate in selected cases when time constraints and financial reasons make it an alternative to conventional crown and bridgework.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Single case study or anecdote (continued)	Case report of malocclusion with abnormal head posture and TMJ symptoms.	Kondo E, Aoba TJ	Am J Orthod Dentofacial Orthop 1999; 116(5):481-93	Surgery (*Orthodontics, orthopedic surgery, and physiotherapy*)	2	456 weeks (8y10m) (Pt#1); 456 w (Pt#2)	(Pt#1) No; (Pt#2) No	No	No statistical analyses reported.	No statistical analyses reported.	(Pt#1) female, 7 to 18 yo; maxillary protrusion and forward head posture; (Pt#2) female, 10 to 19 yo; malocclusion and poor head posture	Occlusion, head position	Early (in development) occlusal improvement, combined with orthopedic surgery of the neck muscles, was found to be effective.
	Regeneration ad integrum of the condyle head in a patient with temporomandibular disorders.	Learreta JA	Cranio 1999; 17(3):221-7	Occlusion (*Electrical deprogramming of masticatory muscles using trascutaneous electrical neurotransmitters and occlusal splint therapy*)	1	~36 w	At one year	No	No statistical analyses reported.	No statistical analyses reported.	Female, 14 yo; had a streptococcus infection leading to TMD	Position of the articular disc and regeneration ad integrum of the condyle head	Results suggest the need for use of electronic elements in order to treat patients with TMD effectively.
	Necrosis of the articular tubercle after repeated injections of sodium hyaluronate in the temporomandibular joint: a case report.	Iida K, Kurita K, Tange K, Yoshida K	Int J Oral Maxillofac Surg 1998; 27(4):278-9	Surgery (*sequestrectomy*)	1	12 w	At 1 month	No	No statistical analyses reported.	No statistical analyses reported.	Male; 46 yo; spontaneous pain and limited mouth opening; had previously received weekly intra-articular injections of sodium hyaluronate for 5 w	Pain, mouth opening	There is "a need for a gentle technique when carrying out TMJ arthroscopy or arthrocentesis."

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline *(for selected outcomes only)*	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Single case study or anecdote (continued)	MRI study of a physiotherapeutic protocol in anterior disc displacement without reduction.	Martini G, Martini M, Carano A	Cranio. 1996; 14(3):216-24	Behavior/ Physical Therapy (*Physical manipulation*)	3	2 w (all three subjects)	No	No	No statistical analyses reported.	No statistical analyses reported.	(Pt#1) male 19 yo; anterinr disc displacement without reduction; locking; clicking (Pt#2) female 56 yo; anterior disc displacement without reduction; locking; clicking; (Pt#3) female 23 yo; anterior disk displacement without reduction; locking; clicking	Range of mandibular motion and disc-condyle relationship	In cases of anteriorly dislocated discs, the disc was repositioned into a normal position relative to the lossa using the manipulation technique.
	Anterior mandibular repositioning in a patient with temporomandibular disorders: a clinical and tomographic follow-up case report.	Sato H, Fujii T, Uetani M, Kitamori H	Cranio. 1997; 15(1):84-8	Occlusion (*Anterior mandibular repositioning with occlusal denture*)	1	60 w	At 25 m	No	No statistical analyses reported.	No statistical analyses reported.	42 yo female; TMJ clicking; mandibular pain on movement; diagnosis of TMD	Tomographic imaging; patient report of symptoms	Results suggest that image analysis of the TMJ is beneficial; careful application of the occlusal device is recommended
	Chronic, progressive limitation of mouth opening.	Spinazze RP, Helfez LB, Bays RA	J Oral Maxillofac Surg 1998; 56(10):1178-86	Surgery (*Coronoidectomy and NSAIDs; surgery (bone excision) and gap arthroscopy*)	1	8 w post-operative	No	No	No statistical analyses reported.	No statistical analyses reported.	Male, 55 yo; lack of mouth opening; trismus	Mouth opening	Presents a complicated TMD case.
	Complex orthodontic problems: the orthognathic patient with temporomandibular disorders.	Thomas PM, Tucker MR	Semin Orthod 1999; 5(4):244-56	Surgery (*Conservative treatment; occlusal splint; orthognathic surgery*)	1	~260-312 w (5-6 years)	At 2 years (a letter from the patient)	No	No statistical analyses reported.	No statistical analyses reported.	Female, 15 to 20 yo; clicking and locking, joint pain; decreased mouth opening	Occlusion; pain	Elucidates principles that should be followed in treatment decision-making

	Title	Author(s)	Citation	Treatment Category (specific treatment)	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Single case study or anecdote (continued)	Rheumatoid arthritis-affected temporomandibular joint pain analgesia by linear polarized near infrared irradiation.	Yokoyama K, Oku T	Can J Anaesth 1999; 46(7):683-7	Behavior/ Physical Therapy (*Linear polarized near infrared radiation*)	4	~4 w	No	No	No statistical analyses reported.	No statistical analyses reported.	4 females; mean age 43 yo; all had rheumatoid arthritis	Mouth opening with/without pain, VAS pain	TMJ pain disappeared in only four treatments; application of linear polarized near infrared irradiation with RA-affected TMJ pain is an effective and non-invasive short-term treatment.
	Sliding plates on complete dentures as a treatment of temporomandibular disorder: a case report.	Zuccolotto MC, Nobilo KA, Nunes L de J, Hotta TH	Cranio 1999; 17(4):289-92	Occlusion (*Occlusal modified splint using dentures with a sliding plate*)	1	12 w	No	No	No statistical analyses reported.	No statistical analyses reported.	Female, 62 yo; "signs and symptoms of TMD"; pain; reduction in the occlusal vertical dimension	Reestablishing the occlusal vertical dimension.	Sliding plates may be of great benefit to completely edentulous patients with painful symptoms that result from alterations in the occlusal vertical dimension and inappropriate condylar positioning.
Expert Opinion	Internal derangements of the temporomandibular joint: the role of arthroscopic surgery and arthrocentesis.	Barkin S, Weinberg S	J Can Dent Assoc. 2000; 66(4):199-203. Review.	Surgery (*Arthroscopic surgery and arthrocentesis*)	NA	NA	NA	NA	NA	NA	NA	NA	Short-term studies exist indicating that arthrocentesis and arthroscopic surgery are efficacious, but similar long-term studies are lacking.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Expert Opinion (continued)	Behavioral and educational modalities.	Dworkin SF	Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1997; 83(1):128-33. Review.	Behavior/ Physical Therapy (*Behavior adjustment and patient education*)	NA	NA	NA	NA	NA	NA	NA	NA	Behavioral and educational treatment modalities constitute a component of virtually every established chronic pain treatment program. It has been shown that treatment of TMD has benefited from such modalities.
	Temporomandibular disorders and science: a response to the critics.	Greene CS, Mohl ND, McNeill C, Clark GT, Truelove EL	Am J Orthod Dentofacial Orthop. 1999; 116(4):430-1.	*NA*	NA	NA	NA	NA	NA	NA	NA	NA	Practitioners should understand TMD in a biopsychosocial framework, by treating patients with conservative and scientifically validated modalities.
	TMJ Orthodontics	Keller DC	Funct Orthod 1996; 13(3):4-6, 8-12, 14 passim	Occlusion (*TMJ Orthodontics*)	NA	NA	NA	NA	NA	NA	NA	Orthodontic positioning	This article is a discussion of the issues surrounding the use of orthodontics to treat TMD.

	Title	Author(s)	Citation	Treatment Category *(specific treatment)*	Sample Size	Study Duration	Follow-up	Blinding	Statistical Significance From Baseline (for selected outcomes only)	Statistical Significance Between Groups	Sample Characteristics	Outcomes measures	Benefit of study
Expert Opinion (continued)	Putting order into temporomandibular disorders.	Laskin MD	J Dent Assoc S Afr. 1997; 52(6):384-5.	*NA*	NA	NA	NA	NA	NA	NA	NA	NA	Draws a distinction between disorders of muscular origin and those of joint origin, and how the treatment should take this difference into account.
	Chewing over temporomandibular disorders.	Wilkinson TM	Med J Aust. 1997; 167(3):117-8	*Various*	NA	NA	NA	NA	NA	NA	NA	NA	Overview of TMD

XV. APPENDIX B: PER-PATIENT COST LITERATURE

Title	Author(s)	Citation	Summary	Findings
Association between TMD treatment need, sick leaves, and use of health care services for adults.	Kuttila M, Kuttila S, Le Bell Y, Alanen P	J Orofac Pain. 1997; 11(3):242-8	The objective of this study was to analyze the relationship between need for treatment of temporomandibular disorders, sick leaves, and use of health care services in a study population of 441 adults. The findings indicated that these were strongly associated.	Subjects with temporomandibular disorders were significantly more often on sick leave, visited a physician more often, and had more physiotherapy and massage than subjects who did not need treatment for temporomandibular disorders.
Medical necessity of orthognathic surgery for the treatment of dentofacial deformities associated with temporomandibular disorders.	Moenning JE, Bussard DA, Montefalco PM, Lapp TH, Garrison BT	Int J Adult Orthodon Orthognath Surg. 1997; 12(2):153-61.	This retrospective study assessed the medical necessity of orthognathic surgery for the treatment of dentofacial deformities associated with temporomandibular joint disorders from a perspective of cost effectiveness, myofascial and masticatory function, and quality of life.	On average, patients spent less money per month on costs associated with their orofacial problem after surgery, and there were fewer visits to the doctor postoperatively.
A common sense approach to TMJ and implant imaging.	Scarfe WC	Ann R Australas Coll Dent Surg. 1998 Oct;14:48-61. Review	The recent development of computer-controlled panoramic imaging has made available to us many special projections which are capable of producing hard tissue images of either the TMJ or a potential implant site in multiple dimensions at lower cost (both financially and in terms of X-ray dose) than the more advanced modalities. These projections can now be incorporated into a clinically determined patient-based protocol and thus provide the clinician with both an economical and common sense approach to diagnostic imaging.	NA
Health care utilization by patients with temporomandibular joint disorders.	Shimshak DG, DeFuria MC	Cranio. 1998 Jul;16(3):185-93.	The claims data base of a large New England managed care organization was used to compare the health care utilization patterns of patients with TMJ disorders to non-TMJ subjects. Inpatient, outpatient and psychiatric claims data were examined over a wide range of diagnostic categories.	Age and sex adjusted results showed that, overall, patients with TMJ disorders were greater utilizers of health care services and had higher associated costs than non-TMJ subjects. For some of the major diagnostic categories, such as nervous, respiratory, circulatory, and digestive, the inpatient and outpatient claims differences in utilization and costs were as large as 3 to 1. For only one diagnostic category, pregnancy and childbirth, were utilization and costs greater for non-TMJ subjects than TMJ patients. The psychiatric claims for TMJ patients exhibited differences that were at least twice as large as those for the non-TMJ subjects.
Medical claims profiles of subjects with temporomandibular joint disorders.	Shimshak DG, Kent RL, DeFuria M	Cranio. 1997 Apr;15(2):150-8.	The primary goal of this study was to evaluate the claims profiles of subjects with TMJ disorders relative to a control group without the disorders and to provide a characterization of the type of healthcare services received and the associated costs of healthcare for patients with TMJ disorders. The administrative data base of a major medical insurer was used to compare the claims history of 1,819 patients diagnosed with TMJ disorders to matched controls. The analysis was based only on medical claims.	The study found that total medical claim payments for the patients with TMJ disorders were double that of the subjects without TMJ disorders, and similarly, the utilization of institutional and professional care services was found to be approximately twice as high, though not uniformly distributed across all Major Diagnostic Categories, physician specialties or types of service.

Title	Author(s)	Citation	Summary	Findings
The TMJ Association 1999 Survey Results	The TMJ Association	Unpublished	A questionnaire was sent to patients that had previously contacted The TMJ Association. The questionnaire requested information on patient characteristics, the nature of the patient's treatment (i.e., surgical implant of not), and the patient's out-of-pocket costs and insurance status.	The survey results showed that the average out-of-pocket costs for non-implant patients was $13,641, and $68,370 for patients with implants. The average out-of-pocket costs for all patients questioned in the survey was $40,164.
Health care utilization and cost among HMO members with temporomandibular disorders.	White AB, Williams LA, Leben JR	In press, J Orafacial Pain	This paper compared the use and cost of medical and dental care services for TMD patients and matched comparison subjects. TMD cases were continuously enrolled members of Kaiser Permanente Northwest Division who had at least one TMD Clinic visit or TMD-related procedure between 1/1/90 and 12/31/95. An equal number of comparison subjects, identified electronically, were matched on 14 variables, including age and gender. Utilization and cost estimates were determined and compared for selected medical and dental services.	TMD cases used more of all types of services and had higher costs (approximately 1.6 times greater than non-TMD patients). A small proportion of the subjects accounted for a large proportion of the costs. Gender was an important factor in utilization and cost. Utilization and cost differences were consistent over a wide range of service categories and could not be explained by TMD alone.